Food·Drug·Cosmetic Law

The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need.

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FOOD DRUG COSMETIC LAW JOURNAL

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About the Authors

Erwin P. Snyder, of the law firm of Snyder, Chadwell & Fagerburg, Chicago, Illinois, is general counsel for Kraft Foods Company. His article in this December JOURNAL is derived from his address before the annual meeting of the American Bar Association's Division of Food, Drug and Cosmetic Law in the Section of Corporation, Banking and Business Law, at Chicago on August 17, 1954.

Another of the ABA papers is that of **Paul Gerden,** general counsel for Abbott Laboratories at North Chicago, Illinois. He has been associated with Abbott since 1949. Prior to that time, he was in the private practice of law in Chicago, excluding the years he spent with the armed forces during World War II.

Mr. Gerden received his undergraduate degree at the University of Illinois and his law degree at the Northwestern University School of Law.

Also in this issue is the annual report of the Food and Drug Administration for the fiscal year 1953, which marked the fifteenth year of the Federal Food, Drug, and Cosmetic Act of 1938. It notes: "Appropriately—a look backward will show the progress of the law since its enactment, while a look at current problems will show unfinished tasks which remain for the years ahead."

Meeting of Food and Drug Men

The Tenth Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association will be held on January 27, 1955, at 42 West 44th Street in New York City. It will provide a valuable discussion of food, drug and cosmetic law and, particularly, the Federal Food, Drug, and Cosmetic Act. Proceedings will be broadcast by Station WNYC, and published in the FOOD DRUG COSMETIC LAW JOURNAL.

Morning Session, beginning at 10 o'clock

Presiding Officer: Chairman of Section

Introductory Statements by the Officers

Charles Wesley Dunn of New York City, Chairman; Fred Bartenstein, Jr., of Rahway, New Jersey, Secretary

Official Discussion of Federal Food, Drug, and Cosmetic Act

Bradshaw Mintener of Washington, D. C., Assistant United States Secretary of Health, Education, and Welfare

George P. Larrick of Washington, D. C., United States Commissioner of Food and Drugs

William W. Goodrich of Washington, D. C., Assistant General Counsel, United States Department of Health, Education, and Welfare

Addresses

Harry J. Anslinger of Washington, D. C., United States Commissioner of Narcotics

Subject: "Adequate Narcotic Drug Control"

Dr. James R. Wilson of Chicago, Secretary, Council on Foods and Nutrition of American Medical Association

Subject: "Influence of Council for Voluntary Food Industry Standards, to Protect and Improve the Public Health"

Dr. Robert R. Williams of New York City, Member, Food and Nutrition Board of National Research Council

Subject: "The Relationship of the Work of the Board to Food Law Enforcement"

Floor Discussion

Notice: All speakers at the meeting are cordially invited to lunch with the officers, chairmen and execu-

(Continued on page 753)

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Journal

ERWIN P. SNYDER Presents

AN APPRAISAL OF THE O'HARA BILL (H. R. 9166, EIGHTY-THIRD CONGRESS) TO PROVIDE FOR THE PRETESTING OF NEW CHEMICAL ADDITIVES TO FOOD

Mr. Snyder, a Chicago Lawyer, Addressed the ABA Division of Food, Drug and Cosmetic Law in That City Last August 17

IT APPEARS that I have been listed as an opponent of this legislation, and I first want to make it plain that I am appearing not as an opponent of chemicals-in-food legislation, but as an advocate of clear thinking on this subject. If clear thinking requires a criticism of the present O'Hara bill or any other similar proposal, please understand that this criticism is being offered in a constructive manner rather than as from an opponent of this type of legislation. In order further to support the characterization of my views on this subject, I should like to point out that for many years I have earnestly advocated the enactment of legislation of this sort because I feel that it is of greatest value to responsible food manufacturers. In my opinion the Federal Food, Drug, and Cosmetic Act in its present form is not so inadequate from the viewpoint of the government as it is inadequate from the viewpoint of the manufacturers of chemicals and foods. I will deal with this point more specifically as I discuss the present law and the changes that would be made therein by the O'Hara bill.

Initially, one should ask why the present food and drug Act is not adequate. The report of the Delaney Committee indicates that the present provisions are inadequate because they place on the government the burden of proving by a preponderance of evidence in a court of law that a chemical added to a food is harmful, that such evidence may not exist and that injury may occur before the government may secure proof that the substance is harmful (House Report No. 2356, Eighty-second Congress, Second Session, pages 21-22). At the same time, let us see why the Act is inadequate from the standpoint of the chemical and food manufacturers.

1906 Act and Poisonous or Deleterious Substances

In order properly to understand the effectiveness of the present food and drug Act it is necessary to examine for a moment the infirmities of the 1906 Act as they related to so-called poisonous or deleterious substances in food. The only such prohibition in the 1906 Act was against a food that contained any *added* poisonous or other *added* deleterious ingredient which might render the food injurious to health. In this respect the 1906 Act was obviously inadequate because it made no reference at all to naturally occurring poisonous or deleterious substances in food. Moreover, in the case of added poisonous or deleterious substances only the particular food in question could be considered in determining the question of injury to health. No consideration at all could be given to the cumulative effect of the presence in the diet of a number of foods, each of which might contain the same or related poisonous or deleterious substances.

As a result of Congressional consideration of these deficiencies, the present food and drug Act contains three prohibitions against poisonous or deleterious substances: one relating exclusively to nonadded or naturally occurring substances and the other two, which are logically inconsistent with each other, relating to added substances. Section 402(a)(1) defines as adulterated any food which contains any nonadded poisonous or deleterious substance in a quantity which would *ordinarily* render the food injurious to health. Section 402(a)(1) also establishes a test with respect to *added* poisonous or deleterious substances, but requires a lesser showing on the part of the government. In this respect it is identical with the 1906 Act, and provides that a food shall be deemed to be adulterated if it bears or contains any *added* poisonous or deleterious substance which *may* render the food injurious to health.

This test is of little or no practical importance to the chemical or food manufacturer because Sections 402(a)(2) and 406(a) (which must be read together) set up a test which, if fully applied, eliminates any possibility of fulfillment. These sections provide in effect that *any* quantity, no matter how minute, of a poisonous or deleterious substance added to a food makes that food adulterated. True, Section 406(a) does contemplate the establishment by the Secretary of Health, Education, and Welfare of tolerances for such added poisonous or deleterious substances, but the terms under which such tolerances may be established are so onerous as to make them of little or no practical effect. As a matter of fact, I know of no instance in which the procedure established in Section 406(a) has been employed, although attempts were made to use it to establish tolerances for pesticides.

The basic fallacy inherent in Sections 402(a)(2) and 406(a) lies in the fact that these sections are based upon the view that all substances may—without reference to quantity, method of use, etc.—be classified as either toxic or deleterious substances, on the one hand, or nontoxic or nondeleterious substances, on the other. This method of classification, frequently referred to as the "per se" or "black and white" classification, finds no support either in science or in logic. This is so because a substance has toxic properties only in relation to the quantity thereof that may be present in the food. It has been well said by Bernard L. Oser ("Can a Poison Exist in a Vacuum?" 8 *Food Drug Cosmetic Law Journal* 693, 696 (November, 1953)):

> There is no foundation in toxicology for regarding all substances as either poisonous or deleterious, on the one hand, or safe or harmless, on the other. The optical physicist has his absolute white and absolute black, but there are no absolutes for the toxicologist. "Toxicity" depends on species, age, weight, sex, dosage, route of administration, physiological or pathological state, and manifold other factors comprising "experimental conditions." Translation of toxicity data into terms of real or potential effect under any given set of circumstances as, for example, the determination of hazard to any particular segment of the population or to the public health generally, involves considerations that go far beyond toxicity effects in laboratory animals.

He succinctly sums this up by saying "there is no zero degree of toxicity, of poisonousness, of deleteriousness or, indeed, of hazard."

Despite the basically illogical character of these sections of the statute, they remain nonetheless a very potent and effective weapon in the hands of the Food and Drug Administration when it desires to so use them. It has been held unnecessary for the government, in order

to prove a case, to demonstrate that the food containing a particular added ingredient is likely to be injurious to health. It has been held sufficient to show merely that the ingredient is poisonous or deleterious —that is, that it has a potentiality for harm—and that it exists in some quantity, however minute, in the food. An illustration of the effectiveness of these sections of the Act is found in the case of *U. S. v. Commonwealth Brewing Corporation* (DC Mass., 1945), Kleinfeld and Dunn, *Federal Food, Drug, and Cosmetic Act, 1938-1949*, pages 310, 314-315. While I do not wish to be understood as condoning the use of fluorine in beer, I do submit that it is wholly illogical to determine the toxic character of fluorine by reference to the number of parts per million that might be harmful and then to declare the beer to be adulterated without reference to the quantity of fluorine contained therein.

I strongly advocate the removal from the food and drug Act of these illogical provisions if that can be done without in any manner weakening the control which the Food and Drug Administration presently has over the use of substances in foods which may have a harmful or deleterious effect. I believe this can be accomplished by the O'Hara bill, modified by the suggestions which I am about to make. In addition and, perhaps, most important, such changes in the law would afford responsible food manufacturers the opportunity of using, subject to the control of the Food and Drug Administration, ingredients in food which do not constitute a hazard to public health, but which presently cannot be shown to satisfy the impossible requirements of Section 406(a).

In order to understand why no tolerances for food ingredients have been established under Section 406(a), it is merely necessary to look at its language. In order for a food manufacturer to obtain approval of an ingredient under that section, he must first allege that the substance proposed to be used is poisonous or deleterious, which in any sensible interpretation means that he proposes to use it in quantities which may be injurious to health. Obviously, any responsible food manufacturer is reluctant to make such a statement or admission, particularly in view of the publicity that would undoubtedly be given to such an admission or the proceedings at any hearing that might be conducted. Second, the food manufacturer must be prepared to prove that the ingredient is required or that its use cannot be avoided in the production of the food. This is a clearly impossible burden except, perhaps, in the case of spray residues, which now have been taken out of the operation of Section 406 altogether.

What responsible food manufacturers have long desired is some procedure which will permit them to use a substance that has been adequately pretested to show that when it is used in the quantity proposed it will not create any hazard to public health, and which will permit this without the impossible burden of showing that without it the food cannot be produced. I certainly do not believe that food manufacturers should be permitted to use indiscriminately chemicals which involve a hazard to health. If it can be demonstrated that the use of the ingredient involves no measurable health hazard, it would seem that mere convenience or desire would be sufficient ground to sanction its use. On the other hand, if the health hazard is extremely great, a showing, similar to the showing now necessary under Section 406(a), that the use of the ingredient is required might be appropriate, with the result that in some cases the character and degree of the hazard might prevent any food use of such ingredient. Where the hazard falls somewhere between these extreme limits, a corresponding showing of benefits—including economic ones—must be made. In other words, a person desiring to use a new chemical additive should be required to show reasonable grounds for such proposed use.

Proper and Adequate Consideration of Chemicals

In this connection I do not wish to be understood as advocating that the Food and Drug Administration, in evaluating the hazard to health of a food containing a chemical additive, should be restricted to a consideration of that food or that chemical alone. I fully agree that it is proper for the Food and Drug Administration to take into consideration in determining health hazard not only the use of the particular chemical in a particular food, but also the use of such chemical in other foods, as well as the use of all related chemicals that may have harmful potentialities in all foods that may enter the diet.

With these introductory remarks I will now turn to an analysis of H. R. 9166, the so-called O'Hara bill. The suggestions for changes in this bill are not intended as final or conclusive. They may very well not represent the best means of accomplishing the desired end in each instance. What I sincerely hope they will do is serve to illustrate the principles that should be embodied in legislation of this sort in order, first, to protect the public health and, second, to foster and promote continued research in the food industry and to make possible the application of the fruits of such research.

The first section of the O'Hara bill defines the term "new chemical additive." In essence, it defines this term to mean any substance which is not generally recognized among qualified experts as being safe for use in foods. In my opinion this definition is basically sound, for it makes it unnecessary to submit for prior approval all ingredients that may have been or may in the future be used in foods. It is only those ingredients about which there is some question of safety for food use that are required to be submitted to the Food and Drug Administration for approval. However, I believe the definition is deficient in failing to give adequate recognition to the quantity and intended use of the new chemical additive. These factors should be included in the definition with great particularity. For this reason I believe that the last few words of the definition found in lines 7 and 8 on page 2 of the bill, where it states that the chemical is one generally recognized as "not to be a poisonous or deleterious substance for its intended use," should be changed to define a new chemical as one generally recognized "not to be *such* a poisonous or deleterious substance *when used in the quantities and manner* intended as may render the food in or on which it is intended to be used, injurious to health."

Objections to Section 2 of O'Hara Bill

Section 2 of the O'Hara bill amends Section 402(a)(2) of the food and drug Act. I seriously object to this section of the O'Hara bill because it would continue the present illogical provisions of Sections 402(a)(2) and 406(a). In this connection I note that it is not proposed in the O'Hara bill that any change be made in Section 406(a). Now that pesticides have been treated separately in Section 408, I see no reason to continue Section 406(a) in the Act, for the report of the Delaney Committee (at page 22) states the primary purpose of Section 406 to have been to provide a means for fixing tolerances for spray residues on foods. I would eliminate entirely the clause in Section 402(a)(2) which presently provides that a food is adulterated "if it bears or contains any added poisonous or added deleterious substance except a pesticide chemical in or on a raw agricultural commodity which is unsafe within the meaning of Section 406." Instead, I would have Section 402(a)(2) read as follows:

> A food shall be deemed to be adulterated—
>
> If it is or if it bears or contains any new chemical additive which is unsafe within the meaning of Section 409(a) or if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of Section 408(a). . . .

Advantages of Proposed Wording

This proposal would give the Food and Drug Administration exactly the same degree of control over the addition to food of substances having a poisonous or deleterious effect as it presently has under Sections 402(a)(2) and 406(a). In order for the Food and Drug Administration to proceed under the present law it must show that the ingredient complained of is in or on the food in a demonstrable quantity. In addition, it must show that the ingredient complained of is poisonous or deleterious. This latter element is proved by the opinion testimony of qualified experts. Under my proposal, the issues and quantum of proof will be virtually identical. The Food and Drug Administration will, of course, still be required to show that the ingredient complained of is in or on the food in a demonstrable quantity. It will then be required to prove that such ingredient is, in the opinion of qualified experts, unsafe for use in foods and that the Food and Drug Administration has not authorized its use under Section 409. The expert-opinion testimony will be adduced in the same manner and addressed to essentially the same issue as is presently the case under Sections 402(a)(2) and 406(a). Accordingly, it can be seen that there is no real difference in either the manner or degree of proof under my proposal and under the law as it presently exists. The very definite advantage of the proposal which I have suggested is that it is realistic, scientific and logical in its approach.

Accordingly, I would eliminate entirely from the Act the language presently appearing in Section 406(a). Section 406 would then consist solely of the provisions presently found in Section 406(b) relating to harmless coal-tar colors.

The same change that has been suggested with respect to the definition of the term "new chemical additive" must also be made in a number of other places in the O'Hara bill. The first of these places is in Section 409(a), lines 7 and 8, on page 3 of the bill so that the language which presently reads "the new chemical additive is not a poisonous or deleterious substance for its intended use" will be changed to read "the new chemical additive is not such a poisonous or deleterious substance when used in the quantities and manner intended as may render the food in or on which it is intended to be used, injurious to health." This same change must also be made in Section 409(b) in lines 12 and 13 on page 3; in Section 409(b)(G) in lines 8 and 9 on

page 4; in Section 409(c) in lines 20 and 21 on page 4, lines 3 and 4 on page 5, and again in lines 6 and 7 on page 5; and finally in Section 409(d) in lines 13 and 14 on page 6.

Changes in Certain Requirements of Application for Approval Suggested

I believe that the information required to be shown in the application for approval of a new chemical additive is basically reasonable and necessary. However, I do believe that changes in certain of the requirements would clarify the situation for the applicant. The first such change is in subsection (A) of Section 409(b), which requires a statement of the name, chemical identity and composition of the new chemical additive. In recognition of the fact that all of this information may not be available for each substance falling within the definition of new chemical additives, I would suggest that this be changed so that it would require a showing of the name and all pertinent information concerning the new chemical additive, including—where available—its chemical identity and composition. The second requirement of the application is a statement of "the proposed use of the new chemical additive, together with functional use information." While the term "functional use information" is not completely without question, I assume that it comprehends information with respect to the benefits to be expected from the use of the ingredient in foods. In this connection I assume the information called for by this requirement is similar to that required under subsection (H) of Section 409(b), which requires the applicant to show reasonable grounds in support of his application. If this is what is intended by these requirements, I fail to see any basis for criticism of them, as they are clearly necessary for an intelligent appraisal of the application. The third requirement of the application is "a full description of the methods used in, and the facilities and controls used for, the production of the new chemical additive." In my opinion this requirement is deficient in not requiring the same information with respect to the food to which it is proposed the ingredient be added. Accordingly, I suggest that this provision be amplified by adding, at the end of it, the language "and of the food in or on which it is intended to be used." In some instances this requirement may involve the disclosure of trade secrets in the production of the chemical additive or its use in foods. In order to protect an applicant against improper use of such information, the penalties of Section 301(j) of the Act relating to the disclosure of trade

secrets should be extended to procedures under Section 409. The fourth requirement of the application is "a description of the methods for quantitative determination of the new chemical additive, and its reduction products, in or on food." This seems to suggest that an application may be made for the use of a chemical additive in foods generally. I do not believe that this would be desirable. I feel that an application should be addressed to a specific use of a chemical additive in or on a specified food or foods. For this reason I suggest that instead of saying "on food" the wording should read "on the food."

I do not want to pass by this requirement of the application without observing that it gives great cause for concern. To a layman such a requirement seems reasonable, but I have been informed by competent technicians that there are many substances falling within the definition of a new chemical additive for which there may not be quantitative methods for determining their presence or, more particularly, the presence of their reduction products in or on the food. An application for the use of such an ingredient, particularly one with a low order of toxicity, should not be denied for failure to fulfill this requirement. This requirement should have additional study, and I earnestly suggest that those who are familiar with these technical aspects of the problem give it further consideration.

The fifth requirement of the application is a statement of "all directions, recommendations and suggestions proposed for the use of the new chemical additive including specimens of its proposed labeling." It would certainly seem equally important that the proposed labeling of the food in or on which the new chemical additive is intended to be used be set forth in the application as well. For that reason I suggest amending this requirement by adding at the end the following language: "and the proposed labeling of the food in or on which its use is intended."

A similar observation must be made with respect to the sixth requirement, that "full reports of investigations made with respect to the toxicity or other potentiality for harm of the new chemical additive" be supplied. Actually, such information with respect to the food in which the chemical additive is used is of much greater relevancy and importance. I would suggest that the language "and of the food in or on which it is intended to be used" be added at the end of subparagraph (F).

The seventh requirement—namely, that a proposed regulation be submitted by the applicant—is certainly a reasonable one, and the

same is true of the requirement in subparagraph (H) that the applicant show reasonable grounds in support of his application. However, the requirement in subsection (H) that "samples of the new chemical additive and of articles used as components thereof shall be furnished to the Secretary upon request" appears objectionable on two counts. In the first place, it may not be possible in all cases to submit articles used as components "of the new chemical additive." Second—and this is even more important than the first objection—there should be a requirement that the applicant furnish samples of the food in or on which the chemical additive is used. I suggest that appropriate amendments be made to reflect these changes.

Now let us turn to a consideration of the test or yardstick to be employed by the Secretary in determining whether the chemical additive is safe for food use as set out in Section 409(c) on page 5 of the bill. I suggest a substantial revision of the first such standard, which presently reads "the functional value of the proposed additive for its intended use." In my opinion this is so vague as to be virtually meaningless. Accordingly, I would suggest that it be rewritten so the Secretary may consider "the possibility of danger to public health as compared with the potential economic and other benefits likely to result from the use of such new chemical additive in or on the food." My reasons for this suggestion are clearly apparent in view of my earlier remarks concerning the necessity for balancing the hazard to public health against potential benefits to be achieved from the use of the chemical additive in or on the food.

The second such test relates to the probable consumption of the new chemical additive and any food *in* which it is intended to be used as a component. This should be changed to make it clear that the chemical additive might possibly be used *on* the food as well as *in* the food.

The third test presently reads: ". . . the cumulative effect in the diet of the same *or* any chemically or pharmacologically related substance or substances." It seems apparent on its face that the word "or" at the beginning of line 14 should be "and," because the Secretary should certainly be permitted to consider the cumulative effect of the sum total of both the chemical additive in question and any other substance related thereto either chemically or pharmacologically.

I have several criticisms to make of the procedure established for the consideration of the application by the Secretary and for appeals from the decision of the Secretary. While the bill contemplates that the Secretary should take action upon applications within specific

times that are set forth therein, there is no provision with respect to what happens in the event the Secretary for one reason or another should fail to act within the time limited. In order to eliminate the possibility of a continuing failure on the part of the Secretary to act on an application, I would suggest that a provision similar to that found in the new-drug section of the Act (Section 505(c)) be incorporated—that unless the Secretary denies an application within a reasonable period of time, such as six months, the application should be deemed to have been granted. In this connection there should be a requirement that the Secretary rule on all applications within such time, even though the Secretary may consider an application to be incomplete.

It appears to be the intention of Section 409(c) to grant to an applicant the absolute right to request reference of his application to an advisory committee within 120 days after the filing thereof, even though the Secretary may deny the application prior to the expiration of such 120-day period. However, it is not completely clear that this intention has been appropriately expressed and there is some basis for contending that such a reference can be requested only within the 120-day period *and* prior to any denial of the application by the Secretary. Furthermore, no provision is made for the situation where the Secretary may deny the application on the final day without there having been a prior reference or request for reference to an advisory committee. Moreover, subsequent provisions of the bill providing for court review of action by the Secretary provide only for the review of orders where an advisory committee has considered the application; there is no provision for court review of the denial of an application which has not been considered by an advisory committee. While there may be circumstances which would justify streamlining the application procedure by making it unnecessary for an advisory committee to be convened and to consider every application that is filed, it certainly is grossly unfair to deprive an applicant of the right to a court review under such circumstances. In addition, unless there has been a referral of the application to an advisory committee, there is no requirement that the Secretary state his reasons for any denial nor any requirement that he make and publish findings of fact in support thereof. Accordingly, I suggest either that an advisory committee be convened to consider each application filed or, in the alternative, that the applicant be given the same right to a judicial review where there is no reference to an advisory committee as he is in the case where an advisory committee does consider the application.

Section 409(e) and (h)(2) of Federal Act Examined

There is language in subsection (h)(2) and also in subsection (e) of Section 409 which could possibly be interpreted to mean that the "report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee" constitute in themselves substantial evidence in support of the regulation promulgated by the Secretary. The language in subsection (h)(2) which could be so interpreted is found in lines 23-25 on page 9 of the bill, and in lines 1-2 on page 10. It reads:

> The findings of the Secretary with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole, including any report and recommendation of an advisory committee.

The language in subsection (e) which may be susceptible of this interpretation is found in lines 15-19 on page 7 of the bill. It reads:

> Such regulation shall be based only on substantial evidence of record at such hearing, including any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee. . . .

To eliminate the possibility of such an unintended interpretation I would do two things: First, I would broaden the language of subsection (h)(2), which now refers only to the "report and recommendation of an advisory committee," so that it would include also the "underlying data and reasons certified to the Secretary." Second, I would make it clear that the report, recommendations, underlying data, and reasons of the advisory committee are enumerated as being illustrative of the contents of the record rather than for the purpose of suggesting that these documents constitute substantial evidence. This could readily be done by changing the language of subsection (h)(2) so that it would read:

> The findings of the Secretary with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole, which record shall include any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee.

A corresponding change should then be made in subsection (e). This change will insure proper application of the substantial-evidence rule as laid down by the Supreme Court in the case of *Universal Camera Corporation v. National Labor Relations Board*, 340 U. S. 474 (1950).

One final matter that appears worthy of mention is the fact that this bill does not contain any specific grant of authority to the Secretary to suspend or revoke an application previously granted if it should

be subsequently found that the new chemical additive is actually unsafe for its intended use or that the application contained any untrue statement of a material fact. While this authority is perhaps implicit in the position of the Secretary, it would seem that some advantage is to be gained by including in the bill a section similar to Section 505(e) of the present Act, spelling out with particularity the Secretary's rights in this respect.

The objectives sought to be accomplished by the O'Hara bill are basically sound and, I believe, with the changes in the bill suggested here, such objectives may be achieved. The advance approval by the Food and Drug Administration of chemical additives to food which such legislation will afford should be recognized as being of immeasurable value to the manufacturers. Furthermore, this legislation will remedy an inadequacy pointed out by the Food and Drug Administration. However, I have no intention of being dogmatic and implying that the proposals which I have made are the only ones which could be made to cure the deficiencies of the present Food and Drug Act and of this legislation, but it is my sincere hope that my comments will serve to focus attention upon the problems demanding a solution and will result in a bill acceptable to all. **[The End]**

Appendix

83D CONGRESS
2D SESSION

H. R. 9166

IN THE HOUSE OF REPRESENTATIVES

MAY 17, 1954

Mr. O'HARA of Minnesota (by request) introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

A BILL

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of new chemical additives which have not been adequately tested to establish their safety.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 201 of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end thereof the following new paragraph:

"(s) The term 'new chemical additive' means any substance the intended use of which results or is likely to result in its becoming a component of any food, including substances intended to preserve or alter the food or for any other purpose in manufacturing, producing, processing, packing, wrapping, transporting, or holding the food, which is not generally recognized, among experts qualified

by scientific training and experience to evaluate the toxicity or other potentiality for harm of such substances, as having been adequately shown through scientific procedures or through prolonged use in food not to be a poisonous or deleterious substance for its intended use. The term does not include pesticide chemicals in or on raw agricultural commodities."

SEC. 2. (Clause (2) of section 402(a) of the Federal Food, Drug, and Cosmetic Act is amended to read as follows:

"(2) (A) If it bears or contains any added poisonous or added deleterious substance, except a pesticide chemical in or on a raw agricultural commodity, which is unsafe within the meaning of section 406; or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408(a); or (C) if it is or if it bears or contains any new chemical additive which is unsafe within the meaning of section 409(a);".

SEC. 3. Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end thereof the following new section:

"NEW CHEMICAL ADDITIVES

"SEC. 409. (a) UNSAFE CHEMICAL ADDITIVES.—Any new chemical additive shall be deemed unsafe for the purposes of the application of clause (2)(C) of section 402(a) unless a regulation has been issued by the Secretary pursuant to paragraph (c) of this section announcing that the new chemical additive is not a poisonous or deleterious substance for its intended use.

"(b) APPLICATION TO SHOW SAFETY.—Any interested person shall have the right to file with the Secretary an application containing scientific data for the purpose of establishing that a new chemical additive is not a poisonous or deleterious substance for its intended use. The application shall contain data showing—

"(A) the name, chemical identity, and composition of the new chemical additive;

"(B) the proposed use of the new chemical additive together with functional use information;

"(C) a full description of the methods used in, and the facilities and controls used for, the production of the new chemical additive;

"(D) a description of the methods for quantitative determination of the new chemical additive, and its reduction products, in or on food;

"(E) all directions, recommendations, and suggestions proposed for the use of the new chemical additive, including specimens of its proposed labeling;

"(F) full reports of investigations made with respect to the toxicity or other potentiality for harm of the new chemical additive;

"(G) a proposed regulation announcing that the new chemical additive is not a poisonous or deleterious substance for its intended use; and

"(H) reasonable grounds in support of the application. Samples of the new chemical additive and of articles used as components thereof shall be furnished to the Secretary upon request. Notice of the proposed regulation shall be published in general terms by the Secretary within thirty days after filing.

"(c) ACTION ON APPLICATION.—As soon as practicable after the filing of the application, and in no event more than one hundred and twenty days thereafter, the Secretary shall issue a regulation announcing that the new chemical additive is not a poisonous or deleterious substance for its intended use or shall notify the applicant that no such regulation will be issued: *Provided, however,* That

within the one-hundred-and-twenty-day period the applicant may require that the application be referred to an advisory committee or the Secretary may make such a referral, in either of which case the matter shall await the action of the advisory committee. No such regulation shall issue unless the scientific data submitted establish that the new chemical additive is not a poisonous or deleterious substance for its intended use.

"The Secretary shall, in determining whether the proposed ingredient is a poisonous or deleterious substance for its intended use, consider among other relevant factors—

"(1) the functional value of the proposed additive for its intended use;

"(2) the probable consumption of the new chemical additive and any food in which it is intended to be used as a component;

"(3) the cumulative effect in the diet of the same or any chemically or pharmacologically related substance or substances; and

"(4) Appropriate safety factors for transposing animal experimentation data to practical use in appraising the hazard to man.

"(d) REFERENCE TO ADVISORY COMMITTEE.—In the event the person filing the application requires that the application be referred to an advisory committee, or the Secretary deems such referral necessary, the Secretary shall forthwith submit the application and other data before him to an advisory committee to be appointed in accordance with paragraph (f) of this section. Within sixty days after such referral, or within an additional thirty days if the committee deems such additional time necessary, the committee shall, after independent study of the data submitted to it by the Secretary and other data before it, certify to the Secretary a report and recommendations on the proposal in the application, together with all underlying data and a statement of the reasons or basis for the recommendations. Within thirty days after such certification, the Secretary shall, after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, make public a regulation announcing whether the scientific data establish that the new chemical additive is not a poisonous or deleterious substance for its intended use and the reasons for his action. Such regulation will be effective upon publication.

"(e) OBJECTION TO REGULATIONS; PUBLIC HEARING ON OBJECTIONS; FINAL ORDER.—Within thirty days after publication, any person adversely affected by a regulation published pursuant to paragraph (d) of this section may file objections thereto with the Secretary, specifying with particularity the reasons the regulation is deemed objectionable, and requesting a public hearing upon such objections. The Secretary shall thereupon, after due notice, hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. Any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee shall be made a part of the record of the hearing, if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U. S. C., sec. 1006(c)). The advisory committee shall designate one of its members to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the applicant, or the officer conducting the hearing: *Provided,* That this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearing, the Secretary shall act upon such objections and by order make public a regulation. Such regulation shall be based only on substantial evidence of record at such hearing, including any report, recommendations, underlying data, and reasons certified to the Secretary by an

advisory committee, and shall set forth detailed findings of fact upon which the regulation is based. No such order shall take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

"(f) APPOINTMENT OF ADVISORY COMMITTEE.—Whenever the referral of an application to an advisory committee is required under this section, or the Secretary otherwise deems such referral necessary, the Secretary shall forthwith appoint a committee of competent experts to review the application and to make a report and recommendations thereon. Each such advisory committee shall be composed of experts qualified in the subject matter of the application and of adequately diversified professional background selected by the National Academy of Sciences: *Provided,* That in the event of disability or refusal of the National Academy of Sciences to act, the Secretary shall select such a committee. The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance.

"(g) RIGHT TO CONSULT ADVISORY COMMITTEE.—A person who has filed an application or who has required the referral of an application to an advisory committee in accordance with the provisions of this section, as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with any advisory committee provided for in paragraph (f) of this section in connection with the proposal.

"(h) JUDICIAL REVIEW.—(1) In a case of actual controversy as to the validity of any order under paragraph (e) of this section, any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

"(2) A copy of the petition shall be forthwith served upon the Secretary, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the proceedings and the record on which he based his order, or such parts of such record and proceedings as may be required by court rule. Upon such filing, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole, including any report and recommendation of an advisory committee.

"(3) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

"(4) The judgment of the court affirming or setting aside, in whole or in part, any order under paragraph (e) of this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order. The courts shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

"(i) AMENDMENT AND REPEAL OF REGULATIONS.—The Secretary shall prescribe by regulations the procedure by which regulations under this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of regulations, including the appointment of advisory committees and the procedure for referring applications to such committees."

SEC. 4. There are hereby authorized to be appropriated, out of any moneys in the Treasury not otherwise appropriated, such sums as may be necessary for the purpose and administration of this Act.

EFFECTIVE DATE

SEC. 5. This Act shall take effect upon the date of its enactment.

• PROPOSED REGULATIONS—PESTICIDES •

Proposed regulations to establish safe limits or to prohibit pesticide-chemical residues on fresh fruits and vegetables were announced on October 20 by the United States Department of Health, Education, and Welfare. The regulations cover pesticides ranging from some which are virtually harmless to some which are among the most potent poisons known. The proposed regulations, in two parts, appeared in that day's *Federal Register*.

The first regulation proposed tolerances for 26 pesticides in common use, based on scientific data developed at hearings held in 1950 under Section 406 of the Federal Food, Drug, and Cosmetic Act. Sixty days were allowed for parties who appeared at the hearings to file exceptions to this proposal.

The second regulation sets up the operating procedure under the new Miller pesticide-chemicals amendment (Public Law No. 518), which President Eisenhower signed into law on July 22, 1954. Sixty days were allowed during which interested persons might submit their views in writing and request a hearing if they so desired.

Under proposed regulations, any of the listed fruits and vegetables could legally be distributed in interstate commerce if they did not carry more than the specified tolerance of a permitted pesticide. But combinations of pesticide residues with related pharmacologic effects would be limited so that the total amount of combined residues will be safe.

The proposed regulations provide that *no* residues of the following pesticides shall remain on fruits or vegetables, that is, these pesticides shall have a tolerance of zero: calcium cyanide, dinitro-*O*-sec. butylphenol, dinitro-*O*-cresol, hexaethyl tetraphosphate (HETP), tetraethyl pyrophosphate (TEPP), hydrocyanic acid, mercury-containing compounds, nicotine and nicotine-containing materials, and selenium and selenium-containing compounds.

A Further Review of the

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IN THE EVOLUTION of the federal laws relating to foods and drugs there has been a decided trend toward controls of a type customarily used in the regulation of industries dealing with public utilities, transportation and communication.[1] Because the production and marketing of foods and drugs intimately concerns the health of the public, certain of the controls evolved are undoubtedly necessary, but there are controls presently in effect, sometimes called predistribution controls, which are believed to be an unnecessary and undesirable extension of government into the affairs of its citizens. The proper scope of legislation dealing with the food and drug industries has heretofore been stated to be:

> . . . the philosophy of objectively regulating the conduct of such industry as required by the public interest, to prevent what is injuriously wrong and to command what is beneficially right; whereby its members are otherwise . . . left free to achieve the economic success won in a competitive order, by their individual business efficiency and public service. An exception to this philosophy, for the substitution of a government permission control over private industry, is only justified to the extent it is unavoidably essential to assure the public safety.[2]

This trend was noticeable in the enactment of the Federal Food, Drug, and Cosmetic Act of 1938[3] (hereinafter referred to as the Act), for it contained provisions, in addition to those generally applicable, seemingly extreme but which, in general, have been now accepted as probably desirable.[4] Two of these provisions, relevant to this discus-

[1] See, for example, Meat Inspection Act, 34 Stat. 674, as amended; Virus, Serum, Toxin and Analogous Products Act of 1913, 37 Stat. 832; Virus, Serum and Toxin Act of 1944, 58 Stat. 702; Clutter, "Federal Control—A Problem in the Drug Industry," 6 *Food Drug Cosmetic Law Journal* 936 (December, 1951); Alsberg, "Some Economic Consequences of Commodity Control," 1 *Law and Contemporary Problems* 44 (1933).

[2] Dunn, "Our Food and Drug Law, with Some Observations on its Major Statute," 9 *Food Drug Cosmetic Law Journal* 383, 394 (July, 1954).

[3] 52 Stat. 1040, as amended, 21 USC Secs. 301, and following; see Hoge, "An Appraisal of the New Drug and Cosmetic Legislation," 6 *Law and Contemporary Problems* 111 (1939).

[4] See Clutter, work cited; Cavers, "The Food, Drug, and Cosmetic Act 1938, Its Legislative History and Its Substantive Provisions," 6 *Law and Contemporary Problems* 2 (1939).

Antibiotic Law

This Paper Was Read at the Annual Meeting, Food, Drug and Cosmetic Division, American Bar Association, at Chicago on August 17, 1954

sion, which will be reviewed briefly are (1) the "new-drug" section and (2) the sections relating to certification of coal-tar colors.

The new-drug section,[5] included somewhat in the nature of an afterthought in the Act, was born of the elixir-sulfanilamide tragedy which created a demand for adequate evaluation of the safety of drugs prior to marketing. As proposed, this legislation received scant discussion—probably because of the emergency involved, but perhaps also because of the unpopularity which would have attended one having the temerity to question any aspect of this consumer-protection proposal. Defined broadly is that which is encompassed within the meaning of the term "new drug," and shipment in interstate commerce of any such product is prohibited unless prior thereto there has been filed with the Food and Drug Administration an application by the manufacturer, which includes evidence that the drug:

> . . . is safe for use, when used as directed, and that the manufacturer has the facilities to maintain this safety by maintaining the identity, strength, quality and purity of the drug.[6]

After agency review, this application becomes effective if the Secretary of Health, Education, and Welfare sees no objection to the results of the data so submitted. In the event of disagreement, provision is made for administrative hearings and the opportunity for judicial determination of the issue. This type of drug control has in general met with acceptance primarily because of the capabilities of the individuals in charge of its administration. However, in the hands of an administration so inclined, this law could be used as a vehicle to delay or restrict the marketing of new remedies, for the standard provided—that of safety—is a relative term not susceptible of precise definition or application as to any given commodity.

[5] 52 Stat. 1041, 1052 (1938), 21 USC Secs. 321(p) and 355 (1946).

[6] Nelson, "New Drug Requirements of the Federal Food, Drug, and Cosmetic Act," 4 *Food Drug Cosmetic Law Quarterly* 227, 228 (June, 1949).

The sections relating to certification of coal-tar colors [7] are similar in theory, but different in practice, from the new-drug section. The Secretary is granted authority to promulgate regulations setting forth the coal-tar colors which may be used in foods, drugs and cosmetics, and the manufacturers of these colors must submit samples of each batch produced to the Food and Drug Administration for pretesting by that agency. If the sample so submitted meets the standards established, it is then certified by the Food and Drug Administration as a coal-tar color safe for use in foods and/or drugs and/or cosmetics, and products containing such colors may then, and only then, be shipped in interstate commerce. This procedure gave legal sanction to a practice developed by the Food and Drug Administration without any statutory authority prior to the passage of the Act.[8] Inasmuch as this practice was represented as having proved beneficial to all interested parties, it was the subject of little consideration or discussion in the hearings leading up to enactment.

In 1941, the trend of predistribution controls continued, for the Act was amended to provide for certification of insulin products.[9] Theretofore, the University of Toronto, Canada, holder of the patents on these products, required its licensees in this country to submit to it samples of each manufactured batch for check testing. With the expiration of these patents in 1941, this type of double testing would no longer be required, and it was suggested that the general provisions of the Act relating to drugs were not adequate to cope with the public-health problem so presented. Therefore, the Food and Drug Administration, with the support of the trustees of the *United States Pharmacopoeia* and the American Medical Association, recommended that they be authorized to continue this predistribution testing, citing as precedent the provisions relating to certification of coal-tar colors.[10] The provisions of this law substantially parallel those later enacted in respect of certain antibiotics which will be discussed hereinafter.

With each successive step in the enactment of predistribution controls, precedents for additional controls are established, and it becomes increasingly difficult to oppose further extension thereof or to place limitations on such additions beyond those contained in the previous enactments, and so it was with the law providing for certification of penicillin.

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[7] 52 Stat. 1052, 1055 and 1049, 21 USC Secs. 354, 364 and 346(b) (1946).

[8] See Cavers, work cited.

[9] 55 Stat. 851 (1941), 21 USC Sec. 356 (1946).

[10] H. Rept. No. 1542, 77th Cong., 1st Sess. (1941).

In 1943 the production of penicillin commenced and, under a plan established by the War Production Board—whereby samples from each batch of this product were tested by the Food and Drug Administration prior to release to the armed forces—the possibility of distribution of penicillin low in potency or in any way contaminated was minimized. The reasons for such a program were compelling. Penicillin is a chemical produced by a fermentation process, and in the early years of its production the lack of knowledge regarding this process resulted in a lack of uniformity in the finished batches. Also, the methods of assay then available gave uncertain and variable results.

With increasing production of penicillin, the requirements of the armed forces were soon satisfied, and quantities became available for distribution to meet civilian demands. Inasmuch as the uncertainties of production and assay had not yet been resolved, it was deemed necessary to continue the pretesting by the Food and Drug Administration. To accomplish this, additional legislation was necessary and, as a precedent for it, the provisions relating to insulin were cited. While this proposed legislation was actively supported by all concerned, industry support was predicated on the principle that this was a temporary and not a permanent procedure, and that this type of drug control was not a method to be generally extended. The Food and Drug Administration agreed with these principles, and in 1945 certification of penicillin became mandatory.[11] However, industry was later to learn that the term "temporary" as used by the Food and Drug Administration in support of this legislation was apparently in its geologic sense.

As originally enacted, the law pertained only to penicillin, but later amendments have extended its applicability to include streptomycin, chloramphenicol, chlortetracycline and bacitracin.[12] Under its provisions, the Secretary is directed to promulgate regulations providing for certification of these products if they meet the standards and other requirements prescribed in such regulations. It further provides that such regulations should contain the five following specified types of provisions: (1) standards to be adhered to, (2) tests and assays to be used, (3) periods for which certificates shall be effective, (4) administration and procedures and (5) fees to be paid by the manufacturer.

[11] 59 Stat. 463 (1945), 21 USC Sec. 356 (Supp., 1952); H. Rept. No. 702, 79th Cong., 1st Sess. (1945); S. Rept. No. 410, 79th Cong., 1st Sess. (1945).

[12] Sec. 3, 61 Stat. 12 (1947); Sec. 2, 63 Stat. 409 (1949).

It directs the Secretary to exempt from the requirements of certification products which are (1) to be processed or repacked at establishments other than where they are manufactured, (2) for use in manufacturing other drugs, (3) for investigational use by experts. It further directs the Secretary to discontinue the requirement for certification of any drug or class of drugs when the procedure is no longer necessary. Provision is made for administrative hearing in the event of dissatisfaction with a regulation or the lack of it, with opportunity for court review. Finally, the avenues of interstate commerce are available only for those products which have been so pretested and certified. We are not here concerned with the detailed requirements of the law,[13] but only its broad methods of operation, and an inquiry into its present-day necessity.

FDA Impartiality Emphasized

From an operational point of view, it must be emphasized that there has been little ground for complaint in regard to the services rendered by the division of the Food and Drug Administration in charge of certification. It has provided sufficient technicians to do the requisite testing promptly, and it has facilitated in every way the transmission of its reports. It has developed effective assay methods, and transmitted these to the manufacturers. It has promptly written new monographs for new products whenever needed, has made revisions in monographs and regulations whenever such were indicated, and has advised those affected. It has been fair and impartial.

It has been suggested informally that, through certification, product-liability cases involving such antibiotics could be defended by showing compliance with the regulations. While there are no reported cases involving this certification law where such defense has been attempted, under other laws containing analogous provisions such a defense has not been successful. However, it may be that compliance with regulations pertaining to certification is a question to be considered by the jury in determining negligence.[14] Furthermore, there appears little doubt but that the United States Government could not be interpleaded as a defendant under the Federal Tort Claims Act[15]

[13] For the scope of authority suggested as being contained in the certification law, see Goodrich, "The Applicability of the Federal Food, Drug, and Cosmetic Act to Intrastate Commerce," 3 *Food Drug Cosmetic Law Quarterly* 332, 343 (September, 1948).

[14] See *Ebert v. General Chemical Company*, 310 Mich. 260 (1945); *Paolinelli v. Dainty Foods Manufacturers, Inc.*, 332 Ill. App. 586 (1944); *Ketterer v. Armour & Company*, 247 Fed. 921 (1917); *Presley v. Kinlock-Bloomington Tel. Company*, 158 Ill. App. 220 (1910).

[15] Sec. 403, 60 Stat. 843 (1946), 28 USC 1346, 2671, and following.

in a negligence action, against a manufacturer, based on a certified antibiotic.[16]

It would be pleasant to be able to conclude at this point, and say: "All is well." Unfortunately, there has been increasing dissatisfaction with the operation of the provision which directs the Secretary to promulgate regulations for the exemption from this law of those drugs for which certification is no longer necessary to insure safety and efficacy of use. The operation of this section is dependent upon "the judgment of the Secretary," which has been judicially defined,[17] and the standards established are "safety and efficacy of use." While this language is vague, its intention is clear, for it was adopted to reflect the views of those supporting its enactment: that this entire certification procedure was to be a temporary and short-lived affair. During the nine years of its operation there has been, in my opinion, but token compliance, for in that period but a negligible number of preparations have been decertified.[18] Further, many of the exemptions granted are inconsequential when related to products still certifiable. Several of those decertified are in specified forms only, for which testing and the requisite fee are still required prior to distribution in certain dosage forms.

Record of Industry's Experience

In considering whether there should be additional decertification or certification at all, the record of the drug industry with respect to pretesting of these antibiotics should be of value. The following statistics, compiled from data furnished by the Food and Drug Administration,[19] cover the period from the commencement of certification to April, 1953. During that period, of 80,946 lots of penicillin submitted for certification, .68 per cent were rejected; of 11,370 lots of streptomycin, .62 per cent were rejected; of 1,903 lots of bacitracin, .53 per

[16] *Dalehite v. U. S.*, 346 U. S. 15 (1953); *Toledo v. U. S.*, 95 F. Supp. 838 (1951).

[17] *Federal Security Administrator v. Quaker Oats Company*, 318 U. S. 218 (1942).

[18] Undated release by Food and Drug Administration to manufacturers of antibiotics, issued June, 1954. Products listed as decertified follow: crystalline penicillin G sodium; crystalline penicillin G potassium; antibiotics for diagnostic use; antibiotics for fish diseases; antibiotics as preservatives for bull semen; antibiotics as preservatives for biological drugs; antibiotics for use as ingredients of animal feed for certain prescribed conditions; animal feed mixes intended for certain prescribed conditions; buffered crystalline penicillin G sodium; buffered crystalline penicillin G potassium; certain formulations of penicillin troches; certain formulations of bacitracin ointment; repacked streptomycin sulfate granules (powder), oral, veterinary, provided drug was repacked from certified batch; repacked crude chlortetracycline, oral, veterinary, provided drug was repacked from certified batch; and antibiotics for agricultural use.

[19] 1954 report of general counsel, American Drug Manufacturers Association.

cent were rejected; of 3,780 lots of chlortetracycline, .29 per cent were rejected; and of 1,114 lots of chloramphenicol, 0 per cent were rejected. We must also bear in mind that during the early years of the production of these antibiotics, rejection rates in general ran higher than those indicated, but decreased with each succeeding year so that at the present these rates are considerably lower than stated. This record is one of which the industry may be justly proud. If the experience of industry in the production of these antibiotics is to serve as the criterion for decertification, then on what basis can it be argued that chloramphenicol should continue to be subject to certification, since in the production of this product a perfect record has been maintained. Further, two of the preparations decertified, potassium penicillin and sodium penicillin, have rates of rejection of 1.5 per cent and 1.9 per cent, respectively, and if the rate of rejection affords any basis for decertification—as apparently it must—then there is a large number of products which qualify for decertification when compared with those already so exempted.

Costly Method of Enforcement

It is appropriate, though perhaps delicate, to consider the financial aspects of this type of pretesting. During the period commencing on January 1, 1946, through April, 1954, fees received by the Food and Drug Administration from the manufacturers for certifying their antibiotic preparations exceeded $5 million.[20] At the present time, these fees on an annual basis are running at a rate of approximately $800,000. Based on the actual number of rejections occurring annually during recent years, the cost to ascertain each such rejected batch has been substantial. In comparison with the normal enforcement procedures of the Food and Drug Administration to obtain compliance with the Act, and their probable cost, this appears to be a costly method of law enforcement, and perhaps the point of diminishing returns has been reached. There could be no criticism of this cost to protect the public health if it were the only method available, but this is not the case.

The propositions most frequently advanced to support continued certification of antibiotics[21] are (1) that the production of these products by a biological process is still subject to certain vagaries, and that

[20] See footnote 18.

[21] Crawford, "Legislative and Administrative Progress Under the Federal Food Drug, and Cosmetic Act," 5 *Food Drug Cosmetic Law Journal* 16, 22 (March, 1950); Jester, "Decertification of Antibiotic Drugs," 5 *Food Drug Cosmetic Law Journal* 409 (July, 1950).

methods of testing and assaying continue to produce variable results and (2) that the possibility exists that "persons will enter the field who are neither satisfactorily equipped nor sufficiently experienced to produce antibiotics that are safe and efficacious." [22]

FDA Has Proceeded Against Certified Products

As to the first proposition, scientific people in the industry consider the problems in the production of antibiotics as well settled, and as routine as the production of crystalline sodium chloride. Furthermore, it is generally considered that the testing of antibiotics has been resolved so that the results now obtained are relatively uniform and invariable. There are, and probably always will be, difficulties which arise in the production and testing of any chemical, but these are problems neither inherent in, nor peculiar to, antibiotics. The concern over the production and methods of testing have related more directly to the possibility of antibiotics of less than the declared potency being marketed. The certification approach, while originally deemed necessary as a method to prevent this from happening, has not in practice so operated, for we find that it has been necessary for the Food and Drug Administration to proceed on charges of low potency against the products which they have certified.[23] However, the general enforcement tools provided for in the Act have been, and undoubtedly would continue to be—with or without certification—adequate to cope with these problems.

As to the second proposition, there probably will be persons who enter this field, in the event certification is abolished, who do not have the experience or equipment of the present major producers. If there be a danger in this, there is little doubt that the present vigorous enforcement of the Act could be expanded to cover this anticipated problem. It is presently possible for an inexperienced manufacturer to enter into the field of the production of drugs and produce items of greater potency and more susceptible of harm than the antibiotics,[24] but to my knowledge no enforcement problem has arisen in this connection which the Food and Drug Administration has been unable to control.

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[22] See Crawford, cited at footnote 21.

[23] See "Food and Drug Administration Annual Report," Kleinfeld and Dunn, *Federal Food, Drug and Cosmetic Act* 1938-1949; "1952 Food and Drug Administration Annual Report," 8 *Food Drug Cosmetic Law Journal* 245, 263 (April, 1953); see Jester, work cited.

[24] Products such as digitoxin and tubocurarine, for example.

Standards Not Precise Ones

While the standards set forth in the decertification provision are undoubtedly legally sufficient to support this delegation of authority, and in theory are adequate to protect those affected, in practice it would be extremely difficult to contest the exercise of the judgment of the Secretary, for these standards are not sufficiently precise to afford affected persons with any real remedy in the event of disagreement with an administrative determination. A manufacturer, working day by day with the Food and Drug Administration, would not be readily inclined to engage in extensive hearings if there were little chance of being successful, for fear of disturbing an otherwise friendly and cooperative effort to protect the public health. If, as suggested,[25] this provision is interpreted to provide for decertification primarily on a product basis, a person desiring to accelerate and broaden the decertification of antibiotics could find it necessary to file a series of petitions with the Secretary, requesting the issuance of regulations providing for such exemptions and, inasmuch as there are hundreds of preparations under certification, a modern counterpart of *Jarndyce v. Jarndyce* could well result.

It has been suggested heretofore [26] that the provision relating to decertification be amended so as to establish more definitive bench marks for the guidance of the Secretary in determining which products should be exempted and which would give a more realistic opportunity on the part of an individual to contest the action or inaction of the Secretary. While there is little doubt that when it was originally enacted, the provision for decertification should have contained the foregoing, and while there is little doubt that up to several years ago an amendment of that nature was necessary, there is presently considerable doubt as to the wisdom or necessity of continuing in whole or in part the provisions pertaining to certification of antibiotics. With this doubt existing, an amendment to a part of this law would impliedly sancton the necessity for a continuation of this general type of drug control.

The dissatisfaction with the operation of the decertification provision is predicated in part upon the factors herein presented, but the doubt as to the need of continuing the certification of antibiotics is

[25] See Crawford, cited at footnote 21.

[26] Powers, "Some Aspects of Certification of Antibiotics Under the Federal Food, Drug, and Cosmetic Act," 4 *Food Drug Cosmetic Law Quarterly* 337 (September, 1949); see also "Proposed Antibiotics Amendments," 5 *Food Drug Cosmetic Law Journal* 442 (July, 1950).

further predicated on additional factors. This law pertains only to the five specified antibiotics and their derivatives, but during the period of its operation there have been developed other antibiotics of equal importance and equal potency, and the fears and dangers ascribed to the marketing of the antibiotics we have been discussing would apply equally to this other group. This group includes such important antibiotics as erythromycin, oxytetracycline, neomycin, viomycin, carbomycin and polymyxin. These have been marketed under the provisions of the "new drug" section without difficulty, confusion or dire consequences, and without pretesting by the Food and Drug Administration. There is no evidence, nor to my knowledge has it been suggested, that the marketing of these products without certification has resulted in the failure of these antibiotics to meet proper standards of strength, quality, safety or efficacy. It appears to be understandable why there is concern over the continuance of certification and with the lack of substantial decertification, for apparently it represents a situation wherein extreme controls are continued though the reasons therefor have disappeared. If this concern is correct, then temporizing measures—such as amendments to the certification law—appear to be minor surgery when euthanasia is indicated. If the public health and safety can be adequately protected without such extreme predistribution controls, they should be eliminated, for they then are at variance with the philosophy of the majority of us regarding the proper scope of governmental activities. If the certification law were to be completely eliminated, and it is hereby so suggested, many of the antibiotics would continue to fall within the definition of "new drug" subject to that control. As to those antibiotics which would not be considered new drugs, the general provisions of the Act relating to adulteration and misbranding would be applicable. In the hands of an administration whose ingenuity and tenacity in law enforcement we all respect, there can be no doubt but that any violations of the Act which might arise could be dealt with. If there were need for additional facilities in such enforcement, industry would support the request therefor.

Matter of Conscience to Drug Industry

We in the drug industry have as great a concern over the public health and safety as any other group. While we have volunteered support for measures necessary for the protection of the public, we cannot in good conscience continue to support measures which are no longer needed.

Problem Skillfully Summarized

A distinguished member of the food and drug bar has heretofore made a terse summary of the problem herein discussed, which in conclusion I will quote:

> . . . the antibiotic drug control is in an unsound and chaotic legislative condition—for that government control is inherently designed to be a temporary one, ceasing when the need for it is removed by a safe industry control, whereas it is apparently becoming a permanent one, even though this industry control has been achieved. Moreover, that government control does not reach other antibiotic drugs, in an analagous production situation; its broad extension has been suggested; and certainly this extension should not be made, if and to the extent it is not required by a compelling reason of public safety.[27]

[The End]

Introduction of George P. Larrick, United States Commissioner of Food and Drugs, by Charles Wesley Dunn, General Counsel for the American Pharmaceutical Manufacturers' Association, on the Occasion of Mr. Larrick's First Address Before the Association on December 8, 1954.—

"On July 31 last Mr. Charles W. Crawford retired as the United States Commissioner of Food and Drugs, on the advice of his physician and after thirty-seven years of public service in the administration of our national food and drug law. His retirement was generally regretted by all truly interested in this great public law. . . .

"When Mr. Crawford retired he was succeeded by Mr. George P. Larrick, who thus became the new and present United States Commissioner of Food and Drugs. Mr. Larrick's appointment was clearly indicated in the circumstances. For as Deputy Commissioner he was next in office to Mr. Crawford; his appointment preserved the basic career status and the merit promotion system, which has traditionally and rightly governed the Food and Drug Administration; and there should be no question that it must be completely divorced from any political consideration. We should now add that Mr. Larrick joined the FDA in 1923, as an inspector; and consequently he has been associated with it for thirty-two years. During that period he steadily climbed its official ladder step by step, through sheer ability and hard work and an unqualified devotion to the law he has served. For these fundamental reasons and because he is an expert and competent and just administrator of the highest official integrity, the consuming public and affected industries acclaim his appointment as United States Commissioner of Food and Drugs; and they have confidence that he will duly meet the tremendous responsibility of this high public office. The responsibility of administering the most important commercial law of the land, because it is designed to safeguard the public health by preventing a harmful consumption of essential food and drugs."

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[27] Dunn, "Some Observations on the Food and Drug Law," 8 *Food Drug Cosmetic Law Journal* 39 (January, 1953).

1953

Food and Drug Administration—ANNUAL REPORT

This Report of FDA Describes Some of Its Activities in Fiscal Year 1953 to Enforce a Law Controlling Domestic Products Valued at $50 Billion Annually and Import Products with Invoice Value of Almost $3 Billion

Fifteenth Anniversary Year

"This report marks the fifteenth year of the present Federal Food, Drug, and Cosmetic Act of June 25, 1938, which replaced the original 'Wiley pure food law' of 1906.

"When the act was still in its infancy, its administration was transferred to the Federal Security Agency because its basic purpose was to promote the individual welfare of our citizens. The objectives of the Food and Drug Administration are today identical with those outlined by the President when he recommended to Congress the creation of the Department of Health, Education, and Welfare.

"Appropriately—a look backward will show the progress of the law since its enactment, while a look at current problems will show unfinished tasks which remain for the years ahead.

"The law was a nonpolitical enactment with bipartisan support, primarily to protect the consumer's health and pocketbook, but also to foster fair competition among the regulated industries. Five years of legislative consideration had eliminated practically all disagreement regarding its various provisions. Legal authorities have praised the act as a model of technical legislation.

"As it stands today the law has been strengthened by both legal interpretation and legislative action. Two defects in the original language were disclosed by Supreme Court decisions, both of which led to prompt corrective amendments by the Congress.

"The first of these amendments, adopted by the 80th Congress, made clear that the jurisdiction of the law applies to regulated products

all the way from the point of origin throughout their interstate movement and on through distribution until such products reach the ultimate consumer.

"The second, adopted by the present (83d) Congress (see . . . [page 742, below]) established the right of inspection of all regulated products and the premises where they are manufactured, transported, or held for sale, without advance notice or permission from the owner, operator, or agent in charge.

"The 82d Congress enacted an amendment simplifying controls over the illegal sale of dangerous drugs. Testing and certification of insulin and specified antibiotic drugs which could not be controlled adequately by post-shipment sampling, were established by earlier amendments.

"The courts strengthened the law in numerous decisions reflecting the principle that a statute designed to protect the public should not be read with strained and technical construction that would defeat its purpose.

"Considering that it was enacted on the verge of an era of unprecedented technological change in the food, drug, and cosmetic industries —change accelerated by the greatest war in world history—the 1938 law has been a remarkably adequate and effective statute.

"Particularly fortunate was a provision which required the filing of scientific data to establish the safety of new drugs prior to marketing. This provision anticipated unparalleled advances in chemotherapy which have virtually revolutionized medical practice. Instead of old-fashioned shotgun medication to alleviate symptoms, patients can now be provided with high-powered bullets which cure disease when properly used but which can also do great damage when misused. Manufacturers are constantly striving to improve these new drugs: every change requires an amendment to the original file and a new evaluation. The work load and the responsibility have become greater year by year.

"The need for the new-drug provision of the 1938 act had already been demonstrated at the time of its passage, but post-war changes in the technology of foods and cosmetics could hardly have been anticipated at that time. Would the daily consumption of new ingredients, hitherto unknown for food use, endanger the public? An entire new group of pesticides, tested only for war use under specialized condi-

tions, became available to every food producer and handler, while the scientists were still seeking to learn more about their toxicity.

"Today the housewife buys 'ready-to-heat' and 'ready-to-eat' food, prepared mixes, and washed fresh vegetables in sealed bags. Never before has so little of the actual preparation of the family fare been done in the home kitchen. Control of its wholesomeness and quality have been relinquished to factory management and 'pure food' officials.

"The increase in consumption of packaged and shipped food products, coupled with a 25 percent increase in the population since 1938, is bringing growing complexities in food manufacture, shipping, and storage. The known toxic preservatives in wide use at the turn of the century were quickly abandoned when the 1906 law went into effect, and their use had to be declared on the label. The current additives to foods cannot be handled so simply.

"Apart from provisions for the promulgation of food standards, the food law is corrective rather than preventive. It depends upon investigation, detection, and legal action after products appear on the market, and frequently after large amounts have been consumed. Cooperative efforts of industry and Government to protect the public from potentially harmful food ingredients are entirely on a voluntary basis.

"The situation in regard to new cosmetic ingredients is similar. The disfiguring products of the past have gone, but new, complex chemicals are being employed, sometimes without adequate tests of their safety.

"All such developments have increased the need for new and comprehensive studies and for facilities adequate to deal with a vast expansion in the volume of regulated products.

"The report that follows describes some of the activities of the Food and Drug Administration in the fiscal year 1953 to enforce the law controlling domestic products valued at $50 billion annually, and import products with an invoice value of almost $3 billion. The direct cost was 3½ cents per capita—or about 1/100 of a percent of the value of the goods subject to the Food, Drug, and Cosmetic Act. On July 1, 1952, the Food and Drug Administration enforcement staff numbered 890. At the close of the fiscal year it had dropped to 862 and faced a further reduction of 52 positions because of appropriation cuts.

"The Food and Drug Administration will not slacken activities in protection of health. This will mean decreased coverage in the eco-

nomic field, and to some extent in sanitation. Since many of the economic and sanitary violations are difficult for consumers to detect, the self-interest of the regulated industries to secure a maximum of voluntary law observance will be of increasing importance.

Food, Drug, and Cosmetic Act on Food Front—Health Hazards

"Seizures of dangerously contaminated foods averaged 37 tons a week in 1953 and 14 manufacturers recalled foods and feeds from dealers because of hazards discovered after they were distributed.

"One thousand eight hundred and seventy-five tons of the food seized was wheat treated with a poisonous mercurial compound for seed use and later intermingled with untreated wheat and shipped to flour mills. In the summer of 1952 this grain was colored pink by the compound employed but in June 1953 a carload was seized containing mercury-treated seed that was colorless. Millers who had been rejecting deliveries of the 'pink wheat' could not detect the new treatment by visual examination. The seized wheat was placed under bond and some lots used for the manufacture of non-food products. Other carloads received a scouring treatment under FDA supervision; the unfit scourings were destroyed and the cleaned part released for mill use.

"One packer's entire output of Alaska frozen clams, amounting to more than 10 tons, was seized upon arrival in Seattle because it contained a toxin produced by microscopic marine organisms which is capable of causing paralysis and death in human beings. Due to the incidence of these toxin-producing organisms in many parts of Alaskan waters, there had been practically no packing of fresh or frozen hard shell clams in Alaska for the past 5 years.

"Three seizures were made of a meat preservative containing thiourea to prevent discoloration. This chemical, which was not declared on the label, could have caused thyroid disturbances and other injuries to consumers of the treated meat.

"Two of the recalls involved specialized infants' foods (see Products of Special Dietary Significance).

"The four principal manufacturers of coumarin, on their own initiative, discontinued soliciting sales for food use of this artificial vanilla flavor after they had received reports that it injured the livers of experimental animals. Coumarin has been used extensively in com-

mercial bakery products, packaged cake mixes, ice cream, and chocolate products. The decision to discontinue its sale in food channels, although no case of injury to humans had been reported, is worthy of commendation and indicative of the manufacturers' integrity and high sense of responsibility.

"Another recall took place when 66 college students became ill after eating imitation grape jelly. Investigation disclosed a fluoride contamination; the source was not determined, but the use of salvaged foods in the processing was suspected. The manufacturer recalled and destroyed 9 tons of the jelly.

"Seizure was effected of decomposed eviscerated turkeys destined for school lunch use after illnesses at a number of points were reported. The trouble apparently originated with long delays in transit from the dressing plant to a freezer some distance away. The U. S. Department of Agriculture placed a hold order on all distributions from this plant for sale to the Government under the school lunch program.

Keeping Food Clean

"In volume, nearly 6,000 tons, or about 111 tons a week, of decomposed or filth-contaminated food was removed from consumer channels. Of this, about one fourth had become unfit after it had been shipped by the producer.

"Food factory inspections were cut approximately 3 percent. This was due mainly to the smaller number of available inspectors rather than to refusals to permit inspection after the Supreme Court ruled in December 1952 that the law did not require manufacturers to grant such permission. After this decision there was an immediate response from large segments of the food industry with invitations to continue factory inspections in their plants. While the number of refusals was substantial, the percentage of the total was small. One food manufacturer refused on the grounds that it was not convenient, proper help was not available, 'and besides the plant needs cleaning'. Two days later the inspector returned and the manufacturer said: 'All right, go ahead. I have cleaned up since you were here—no objections.'

"The extent of examination of raw materials in factories and of samples of finished foods in interstate commerce is planned each year with a view to the widest possible coverage of foods most likely to decompose or be attacked by insects and rodents. Adverse growing

TABLE 1.—Actions on Foods During Fiscal Year 1953

Projects[1]	*Seizures*	*Criminal Prosecutions Instituted*	*Injunction Petitions*	*Import Shipments Denied Entry*
Total	1,239	190	6	4,030
Bakery products	13	18	0	63
Beverages and beverage materials	23	8	0	151
Cereals and grain products:				
Human use	220	14	0	19
Animal use	16	9	0	3
Chocolate, confectionery, and other sugar products	49	13	0	261
Dairy products:				
Butter	51	17	0	0
Cheese	11	12	0	92
Miscellaneous	5	0	0	5
Eggs and egg products	16	3	0	0
Flavors, spices and condiments	74	5	0	2,213
Fruits and fruit products	83	8	1	493
Macaroni and noodle products	19	7	0	16
Meat products and poultry	77	27	0	7
Nuts and nut products	95	1	1	105
Oils and fats	3	5	3	6
Oleomargarine	0	7	0	0
Seafood	190	8	1	506
Vegetables and vegetable products	259	12	0	79
Miscellaneous foods and food adjuncts	3	0	0	6
Food for special dietary uses	32	16	0	5

[1] Each project under which action was taken is reported. The total number of food seizures is 1,220 and of criminal prosecutions is 177. (See table 3.) Each of these totals is less than the totals reported above, because table 3 reports combined seizure actions, particularly of warehouse merchandise, and criminal prosecutions against firms that ship foods classified in more than one group.

conditions which affect the fitness of raw materials frequently require an adjustment of these plans.

"The summer of 1952 was a poor season for tomatoes. Heat, blight, and alternating drought and excessive rains brought rot and heavy insect infestation. Few tomatoes had been packed in many areas by late summer. A State canners association expressed the fear that some canners, desperate because they depended completely on the tomato pack for their income, would be driven to using unfit tomatoes.

"Activities of a number of State agencies to control selection of packing stock and keep unfit lots from distribution held Federal

seizures to a normal number. More lots were seized because of fly eggs and maggots, in comparison with decomposition from mold, than in previous years.

"There has been an improvement in the sanitation of poultry dressing plants and the handling of slaughtered birds. Many of the operators have participated in industry-sponsored poultry improvement meetings and demonstrations. The Food and Drug Administration joined State agencies in assisting in this educational program, and also spent considerable time during factory inspections in pointing out to plant managements the precautions necessary to assure an acceptable product.

"The most serious problems found in poultry shipments arose from the inexperience of new operators, and from the slaughtering of diseased and cull birds, which frequently appear on the retail market as cut-up pieces. Other avenues of distribution of diseased and cull poultry have been public eating houses and soup factories that were not careful to reject unfit birds. Recently when a number of soup manufacturers changed their buying policy, merchants of unfit poultry complained that their market was seriously hurt.

"The fish industry is one of the most noteworthy examples of change in consumer buying habits. Before the quick-freeze era, the housewife customarily purchased fish 'in the round' and had it dressed. Today a large portion of the fish on the market is dressed and frozen at the packing plant. Technical men in the industry have shown an increasing tendency to correct conditions that might result in the freezing of decomposed fish.

"There was a materially reduced pink salmon catch in Alaska resulting in heavy importations from British Columbia, which had lost many of its usual European markets. Early importations showed a high incidence of decomposed fish, requiring detention of 5,000 cases of the first 35,000 imported. Corrective measures were taken promptly, and later shipments were free from decomposition.

"Canned salmon packed in Alaska is subject to voluntary industry control which has been generally effective in keeping decomposed lots from the market. In 1953, however, the system did not adequately control the output of an Alaskan cannery jointly operated by three firms. Great confusion as to the identity and location of various code

lots impeded supervision by the industry of code lots ordered destroyed, and a mixture of decomposed and good cans valued at more than $126,000 was seized. The lots were subsequently segregated under bond and the decomposed cans destroyed.

"One Gulf Coast firm was enjoined from shipping unfit crabmeat, after several warnings by inspectors that employees were contaminating the meat by their insanitary habits.

"There was continued improvement in the sanitation of crude vegetable oil mills, discussed in the last report in connection with regulatory work on oleomargarine. A number of mills, however, persisted in using raw materials contaminated with rodent and human filth. Two mills enjoined from shipping crude oils made from unfit soybeans and cottonseed have taken measures to divert large stocks of contaminated raw materials to non-food use, and to provide storage protection for new material received.

"Another injunction was granted against shipment of pecan oil contaminated by curculio insects, cigarette butts, and other extraneous matter. Still another prevented shipment of peanut oil and peanut butter made from 3,000 tons of peanuts contaminated by insects and rodents. The injunction listed under fruit and fruit products restrained a vinegar plant from distributing in interstate commerce 314,300 gallons of vinegar and apple juice made from apples containing rot, insects, and worms.

"The heaviest fine of the year was $10,000 assessed against a macaroni firm and its president for shipping macaroni which was insect infested and prepared in an insanitary plant. Both defendants had pleaded guilty to similar charges in 1947 but they vigorously contested this case in a 3-day trial, and have filed an appeal.

"Heavy import detentions were made of pepper which arrived at U. S. ports, contaminated by insects not previously found in pepper. The infestation was traced to wheat shipments to famine-stricken India from points throughout the world; the overtaxed transportation and storage facilities had been contaminated by many new kinds of insects that were not exterminated before subsequent use for the pepper and other spices.

"Detentions of insect-damaged coffee beans also increased during the year, as a result of high prices which encouraged salvaging of beans that would have been discarded in previous years.

Educational and Regulatory Programs

"Programs designed to effect major improvement in the selection, processing, and handling of raw food materials can best be carried out with the cooperation of industry leaders and various agencies in local, State, and Federal governments. Such programs entail widespread preliminary investigations to evaluate the extent of the problems involved and the corrective facilities available, followed by educational programs to acquaint all groups concerned of the objectives and the procedures planned to achieve them.

"*Wheat and Wheat Flour Program.*—The extensive investigational and educational programs conducted in cooperation with grain trade and milling representatives, the U. S. Department of Agriculture, and the Fish and Wildlife Service of the U. S. Department of Interior during 1950 and 1951, and the regulatory program on wheat and wheat flour inaugurated in the spring of 1952, were discussed in the last annual report. The objective of the program was to reduce filth contamination of food grain by rodents, insects, and birds; eliminate such contaminated grain from milling and other food channels; and reduce the agricultural losses due to the depredations of insects and animals.

"Inspections were made of terminal and country elevators to check on sanitation of storage facilities. This activity was continued during fiscal year 1953 and brought about many improvements in storage facilities and in the protection of wheat in storage. Through the cooperation of trade groups and other Government agencies the slogan 'Grain Is Food—Keep It Clean', was brought to the attention of farmers, grain dealers, and millers via widely circulated publications, posters, and pamphlets and through meetings of trade and agricultural groups. Representatives of the Food and Drug Administration appeared on scores of programs of grain and milling trade associations and farm groups to explain and discuss the grain sanitation program.

"The sampling of cars to check for rodent filth contamination was begun in the fall of 1952 and resulted in seizure and subsequent diversion for animal feed use of 45 cars of contaminated wheat. Examination of wheat for insect infestation was postponed pending development of practicable testing methods.

"In the spring of 1953 the Secretaries of Agriculture and of Health, Education, and Welfare appointed a 17-man committee composed of representatives of the Departments of Agriculture and of Health,

Education, and Welfare; the Fish and Wildlife Service; land-grant colleges; grain producers and dealers; millers and bakers; and sanitarians to make a comprehensive study and review of the problem and to make recommendations to the Secretaries with respect to the grain sanitation program. Further work on sampling cars of wheat has been postponed pending the report of this Grain Sanitation Committee, which met in August 1953 and was organized into subcommittees to study and report on various phases of the problem.

"*Cream and Butter Program.*—Activities in previous years have brought about many improvements in sanitation in creameries and other plants manufacturing dairy products and have caused more care to be exercised in the acceptance of cream and milk for use in manufacturing food products such as butter and cheese.

"Further progress in eliminating filthy and decomposed cream and milk from food channels requires improved techniques in detecting filth contamination and decomposition. During the fiscal year, studies by FDA inspectors and laboratory scientists were intensified. The industry, through a committee sponsored by the American Butter Institute, cooperated in developing improved procedures for detecting filth contamination in cream. The industry group was also active in educational programs to induce producers and dealers to improve the handling of milk and cream to prevent contamination and spoilage. The ultimate objective of this work will be to replace present sampling methods with a test of each can of cream received at the plant, as a part of the processing operation. Present testing procedures are widely variable as to results. Officials in a number of States arranged meetings where representatives of the Food and Drug Administration demonstrated the new testing procedures to industry cream graders.

"*Fresh Produce Markets.*—A series of articles published in *Redbook* Magazine directed public attention to deplorable sanitary conditions in fresh produce markets in a number of cities. One of the articles was the reporter's account of investigations by Food and Drug inspectors. Further inspections made in cooperation with local health authorities, covered produce markets in over 50 cities throughout the country. Seriously insanitary conditions that exposed fresh fruits and vegetables to filth contamination were found in the markets of some localities. In other cities excellent facilities and practices in the handling of produce were found. The worst conditions were observed

in large cities where market facilities had not kept pace with population growth. Overcrowded, antiquated buildings and inefficient facilities contributed to development of insanitary conditions, such as the stacking of produce containers on streets, sidewalks, gutters, and alleyways exposed to street dirt and filth, and contamination by animals and birds.

"Regulatory action in those localities where serious insanitary conditions were found will bring further investigations in cooperation with local authorities. Where there are adequate State or city laws or ordinances, enforcement of the local statutes will be most effective. Sanctions in the Federal statute on produce from interstate sources may be invoked where local statutes are inadequate.

Pocketbook Protection

"In the economic field, the principal problem was to discourage the sale of water at food prices. At least a quart was injected into large turkeys by adapting hypodermic needles designed for the injection of curing solutions in meats.

"September and October inspections of oyster packing establishments in the Chesapeake Bay area surprised the owners, who had not expected visits until just before the Thanksgiving holiday pack. Fifty-nine seizures of watered oysters produced by 24 plants resulted. Packers, responding to citations, stated that the industry had decided to abandon the competitive practice of adding water to oysters in view of the healthier economic situation that had developed as a result of regulatory actions on the part of Federal and State agencies, the latter imposing their own rigid requirements to protect the locally produced oysters. From the first of November until the end of the season, seizures of watered oysters from this area were negligible.

"Five prosecutions were instituted for 'butterlegging' operations. One group, indicted by a Federal grand jury, was reported to have handled in excess of a quarter of a million pounds of oleomargarine during the past year. They were charged with illegal shipments and conspiracy to violate the Federal Food, Drug, and Cosmetic Act. FDA inspectors investigating the plant were at first unable to observe any suspicious operations. After making a floor diagram and measuring the outside of the building, which disclosed unaccounted-for space, they persisted with their search and found a concealed room fully equipped with machinery for processing the oleomargarine so

that it could be packaged as butter. The delivery and manipulation was usually carried on at night. The 'butter' was delivered to a multitude of small grocery stores in the New York area. The case has not yet been tried.

"A corporation and its owner were convicted of distributing, in second-hand bulk butter containers, oleomargarine obtained from one of the individuals under indictment. Although the defendant claimed that he thought he was obtaining butter, the court fined him and placed him on probation for a year with the comment that the defendant was aware of the transactions of his supplier.

"Another case, terminated by a fine and a 1-year suspended jail sentence, came to FDA attention when an inspector noted one brand of 'butter' at a food market offered for several cents below the other brands in the store. Laboratory tests revealed that it was a mixture of colored oleomargarine and butter.

Contaminated Animal Feed

"A great economic disaster to the cattle raisers of the south central area led to the recall of two brands of cottonseed feed. Investigation disclosed that the feed manufacturers were using a lubricant containing chlorinated naphthalene which contaminated the cottonseed pellets they were processing.

"Widespread outbreaks of bovine hyperkeratosis developed in about 25 percent of the herds fed the pellets. State officials monitored the recall and are holding the feed under embargo.

Sea-Food Inspection Service

"Shrimp and oyster canners who meet Government requirements for sanitation and controls are eligible to secure the sea-food inspection service, which is supported entirely by fees paid by participating packers. During the fiscal year, 12 canners packed canned shrimp under inspection; 9 of these also packed oysters. This year's inspected pack was 228,036 cases of shrimp and 79,876 cases of oysters. This represents a slight increase of canned shrimp and a marked decrease of canned oysters packed under inspection.

"The service has been offered to packers of frozen and fresh iced shrimp, but no packers operated under this service during the fiscal year. The regulations for inspection of shrimp were revised so that

in fiscal year 1953 the regulations for canned and frozen and fresh iced shrimp were consolidated.

Products of Special Dietary Significance

"Two of the foods recalled from the market in 1953 were specialized products for the feeding of infants. One was canned dried egg yolk which had been fed to many babies who developed salmonella poisoning. The manufacturers withdrew outstanding stocks and began an immediate investigation of the source of the trouble.

"The second was a product formulated as a substitute for mothers' milk. When convulsions and other disturbances developed in some babies, the manufacturer first attributed the trouble to water in areas which had suffered long drought periods. No chemical or bacteriological contamination could be detected. Later, FDA chemists noted the similarity in symptoms to those observed in feeding experiments 12 years ago with baby rats whose mothers were on a diet deficient in vitamin B_6. Later reports by pediatricians provided some confirmation of the suggestion that the babies were suffering from a vitamin B_6 deficiency. These investigations focus attention on the need for further study on the nutritional adequacy of 'complete' infant formulas.

"The last annual report discussed a new investigation into the accuracy of labeling of low-sodium dietary foods, which are used in the management of certain heart conditions.

"A market survey conducted in the past year revealed general confusion in the labeling of low-sodium items. Some are labeled 'salt (or sodium) free', 'low-salt', 'unsalted', 'packed without added salt', 'for use in low-sodium diets', etc. The less than one-third that bore label declaration of the amount of sodium in the product deviated in terms from milligrams of sodium per 100 grams of food to percentages, and there were wide discrepancies above and below the labeled declarations.

"To add to the confusion, previously reported sodium values of common foods before processing were often in marked disagreement. The Food and Drug Administration has been working with a task committee of the Food and Nutrition Board of the National Research Council to appraise the over-all aspects of low-sodium therapy. It has engaged in collaborative work on methods, the checking of diets for sodium content, a study of salt substitutes, and an extensive tabulation of values reported in scientific literature for the sodium content

of foods. Those whose reported values were in marked disagreement were rechecked by improved methods.

"Over 100 foods with low-sodium declarations were analyzed for sodium content and a number were marked for later regulatory action. Particularly disturbing was the finding that some individuals who were producing foods labeled for low-sodium diets were not aware that ordinary table salt does not have to be present to make items hazardous to persons whose sodium intake must be kept to a low and carefully measured level.

"One product, labeled 'unsalted' broth mix, contained enough monosodium glutamate to supply each serving of broth with 95 mg. of sodium, which is equivalent to about 3 good-sized pinches of salt. Many low-sodium diets are restricted to 250 mg. of sodium for the total daily intake, and this must include natural sodium contained in many foods. Some are so high in natural sodium that they should be excluded from such diets, but canned spinach, beets, and celery juice, which are outstanding examples of foods with high natural sodium content, were found among the 'unsalted' foods in the survey.

"Likewise, some manufacturers are apparently not aware that sodium must be taken into account when they use numerous products designed to leaven baked items; shorten cooking time of cereals; preserve jellies, fruit juices, oleomargarine, and candy; process hominy and peeled fruits; retard molding in bread and cheese; stabilize ice cream and chocolate drinks; and serve other functions adapted to commercial processing.

"The drafting of new regulations was undertaken to provide for the labeling of these dietary foods in terms of their sodium content, so as to enable physicians and heart patients to better calculate the sodium intake.

"The other side of the coin, in regulatory work on special dietary products, is control of foods to which health significance is falsely attributed. Claims that such products will ward off or cure disease without resort to medical treatment have caused much unnecessary suffering and loss of life. Twenty-seven seizures were made of vitamin and mineral products and foods with unfounded curative claims. A heavy expenditure of time is required to cover such violations because the promoters are adept at using indirect means, such as lectures, magazine articles, and other collateral literature, to persuade

the public to buy their wares. Direct claims of curative properties or directions for use in disease treatment are seldom found on the labels.

Drug Traffic

"Forty recalls of defective drugs were monitored in 1953. In 16 instances, the drugs were removed from the market upon the initiative of the manufacturers, and in 24, the recalls were upon FDA request. Voluntary recalls are increasing, in comparison with those forced when defects come to regulatory attention. In many such cases in the past there was a tendency to withhold information while superficial attempts were made to withdraw defective stocks from distribution channels without disclosing the potential dangers involved. Adequate records were available in the past year to trace and withdraw outstanding lots without the necessity of public warnings by the Food and Drug Administration.

"Of the drugs recalled, 13 were below labeled potencies, 9 were nonsterile injection preparations, and 6 were misbranded as to content or directions for use. Among the other defects were injurious ingredients, precipitates, failure to disintegrate (tablets) or melt at body temperatures (suppositories), short volume, and poorly attached labels.

"Of the 150 criminal actions instituted for drug violations, 115 (involving 222 defendants) were based on illegal sales of prescription drugs. In a large proportion of the cases both the firm and one or more salesmen were included in the charges. Some of these actions are still awaiting trial. The remainder, and those not tried at the end of the previous fiscal year, brought 106 pleas or verdicts of guilty in 1953. Three jail sentences were required to be served, two on new actions and one for violation of a 5-year probation ordered in 1951 after a 4-year jail sentence was suspended. Eleven suspended jail sentences were imposed in 1953.

"Violations have moved progressively from those of pharmacists willing to 'take a chance' with customers personally known to them, to deliberate actions, carried out with subterfuge and secrecy, usually involving sales to persons who obviously should not use such drugs without a physician's supervision.

"Refusal by an overwhelming percentage of pharmacists to violate the ethics of their profession has made it possible to concentrate regulatory activities on the fringe operators who are callous to the serious consequences of misuse of dangerous drugs.

"Peddling of barbiturates to inmates of a State penal institution and in a veterans' home was disclosed. Reports received from the penal institution indicated that the source of supply was cut off by FDA prosecution of a drug store not hitherto known to have been supplying the smugglers.

"In another case, a pharmacist was making surreptitious sales of barbiturates to an addict on street corners at designated times, without knowledge of the owner of the store.

"In the same city women seeking to reduce were purchasing amphetamines by 'speakeasy' methods. They presented a white box with an 'X' marked in pencil on the top and gave the password 'tops'. The drug in question should be used only under careful medical supervision.

"One drug store fined for illegal sales could not account by prescription records for 172,552 barbiturate capsules received from wholesalers or manufacturers.

"Again in 1953 a physician was convicted of aiding and abetting illegal sales. He had furnished a druggist with signed blank prescriptions, and whenever the supply of these ran out he signed the prescriptions retroactively.

"Two operators of 'treatment centers' were prosecuted for deliveries of misbranded drugs to be transported for out-of-State use.

"One was an illiterate herb man convicted by a Federal jury after a 6-day trial. He had been treating people from many States for cancer, diabetes, sinus infections, cirrhosis, and other diseases, and sending them home with his herb mixtures. The defendant claimed he had learned the secret of herb medication from his mother, an Osage Indian. At the trial, outstanding authorities in the fields of medicine and pharmacology testified that dependence on his mixtures of mint leaves, boneset leaves and flowers, sunflower and dogwood leaves, and parts of several other plants, supplemented by castor oil and buttermilk, would endanger the lives of those who depended upon them to treat serious diseases.

"The jury heard testimony about a woman whose physician, a cancer expert, had recommended surgery for a small breast cancer in 1947, assuring her of an excellent chance of complete cure. Instead, she went to the herb 'doctor' and took his preparations for 4½ years. At the time of the trial, her lungs and spine were cancer-ridden and she was paralyzed from the hips down. She died soon after the trial. The

defense presented 20 'living testimonials' who told the jury, without scientific evidence, that they had received benefits from real or imaginary diseases. The 'herb doctor' was sentenced to serve a year in jail.

"The second case, terminated with a fine, was against an unlicensed operator of a treatment center who depended largely on walnut bark and mild laxatives for his 'brew'. He suggested that when the patients got their medicine home they add a fifth of whiskey to the 4 quart jars of bark extractives they took with them—for its preservative effects. Hoping to avoid complications with Federal drug laws, he refused to ship refills but referred patients to 'runners' who were transporting people to his place and would obtain additional medicine for them. Several appellate courts have ruled, as did the trial court in this case, that the Food, Drug, and Cosmetic Act is violated when the medicine is offered for interstate transportation, even though the 'doctor' did not personally make the shipment.

"Last year's report discussed an injunction to restrain a cancer clinic from shipping its medicines in interstate commerce, misbranded with cancer claims, which was ordered by an appellate court after the trial court had refused to grant it. In February 1953 the Supreme Court refused to rehear the case and the court of appeals sent an injunction mandate to the district court. The judge refused to issue the injunction decree submitted by the Government, stating that it was too broad. Instead he issued a decree submitted by the defendant's attorney, which would permit marketing the preparations with labeling declaring that there is a difference of competent medical opinion as to the therapeutic value of these medicines in treating cancer. The Government has petitioned the court of appeals to stay and reverse this decree. (In October the appellate court ruled that the language of the decree was in direct conflict with its mandate, and the judge signed the decree originally submitted by the Government.)

"A permanent injunction was granted to restrain a mail order house from shipping a barbiturate treatment for epilepsy. Competent medical authorities agree that an epileptic cannot be adequately treated without personal supervision of a physician.

"Another permanent injunction was granted against further shipments of a product, consisting essentially of rubbing alcohol, which was represented as an effective treatment for arthritis and sciatica.

"For violating an injunction against interstate traffic in an herb preparation, the operator of a 'sanitarium' was fined. Proceedings were instituted for another injunction violation after the apprehension of the defendants, who disappeared for more than a year after citation, but still continued shipments of a worthless diabetes remedy consisting of saltbush, a desert weed. The injunction had been granted in 1941, after futile attempts had been made for many years under the 1906 law to stop traffic in this product which could cost the lives of diabetics. The case charging contempt of the injunction has been set for trial.

"An injunction against further traffic in a drug and device combination for the diagnosis of cancer is discussed under 'Therapeutic Devices'.

"A veterinary remedy seizure, contested by the claimant, involved a preparation that had been relabeled after previous seizures on charges of false and misleading claims for the treatment of bloat in farm animals. The new labeling dropped the direct bloat claims but told farmers it was for 'feeding to sheep and cattle while pasturing in green alfalfa, clover, or in corn and wheat fields'. The Government charged that this meant the same thing to farmers, and the Federal court upheld seizure of the relabeled product.

New Drugs

"Determination of the safety of new drugs before they are permitted to go on the market is determined by evaluating records of pharmacological and clinical studies submitted by the producers. During the fiscal year 1953, drug manufacturers filed 508 new-drug applications for human and veterinary preparations. Four hundred and fifty-four applications went into effect during the year, including a number received late in the previous fiscal year. No applications were rejected, but 13 were withdrawn by the manufacturers.

"Among the important drugs considered during the year were the antibiotics—erythromycin, neomycin, fumagillin, viomycin, and magnamycin; preparations used in the treatment of hypertension—hexamethonium, various purified products of Veratrum and Rauwolfia serpentina; the hormones—hydrocortisone and purified corticotropin (ACTH); a number of antispasmodics used in the treatment of peptic ulcer, such as Antrenyl Bromide, Probanthine Bromide, and Pamine Bromide; an antimalarial—Daraprim; some local anesthetics including

Cyclaine, Ophthaine, Ravocaine, and Dorsacaine; succinylcholine chloride useful for relaxing skeletal muscle during anesthesia; a sulfonamide—Thiosulfil; and two drugs for the treatment of systemic mycotic infections—stilbamidine and ethyl vanillate.

Therapeutic Devices

"An injunction in November restrained further shipments of a cancer diagnosis kit, consisting of a test tube and two bottles of well-known chemicals labeled 'Reagens I and II'. Directions were given to add Reagens I (hydrochloric and nitric acid) to a sample of the patient's urine, heat and cool it, add Reagens II (ether), and if a color change occurred in an hour the patient was doomed as a cancer victim. The kit was employed by many alleged practitioners of the healing arts who had little medical training and no specialized training in the diagnosis or treatment of cancer.

"The danger to public health of such a scheme is emphasized by the fact that controlled tests with this kit showed negative results in 59 of 76 cases known to be malignant, and positive results in many healthy medical students. Retesting on the same group produced varying results. FDA based its injunction request on the fact that the only reliable cancer test is the microscopic examination of suspected tissue by a qualified pathologist.

"Of the 48 device shipments seized, 35 were promoted by false and misleading claims for the prevention or cure of diseases or for weight reduction. Simplest in construction were bags and pads filled with crushed ore from uranium mines abandoned because the radioactivity of the ore was too low for profitable mining operations. 'Ballyhoo' made these mines popular as treatment centers, and more than 100,000 arthritic sufferers paid fees to spend time in the cold, dank shafts seeking to have their ailments cured by the purported radioactive emanations. As long as the operations were localized, they were not subject to the act, but three firms extended their operations to enable patients to 'take the cure' without journeys to Montana. Seizures were made of cabinets, bags, and pads containing the ore, destined for home use and treatment centers in urban communities outside of the State. The radioactivity of the seized ore was less than that from an ordinary luminous-dial watch, and without value in treating arthritis.

"The most elaborate device seized was a pendulum contraption which the manufacturer claimed would swing to the proper position to

diagnose any patient's disease and thereby point to a treatment from among some 90 preparations, mostly vitamin, herb, or vegetable products, including black walnut and violet leaves, poke and sarsaparilla roots, pumpkin seed, citrus peel, juniper berries, yeast, garlic extract, and various dehydrated plants and vegetables, many with a liberal content of chlorophyll.

"Among the other extravagantly promoted devices was an ineffective hearing aid represented as a scientific marvel of the century. Salesmen were instructed to compare it to the miracle drugs. It consisted of a piece of wire twisted to resemble a miniature tuning fork, placed in rubber discs with perforated centers, to be inserted into the ears.

"Devices were seized because of false and misleading claims to remove cataracts and treat other eye conditions; shoes to ward off disease by dispersing the electricity the body generates; violet ray instruments to prevent or cure baldness; and various types of massagers and vibrators to remove excess fat, tone the system, and protect against or cure numerous diseases.

"The electrical vibrator purporting to do the most for the ills of mankind was claimed to be an effective treatment for polio, goiter, diabetes, angina pectoris, appendix pain, locomoter ataxia, cardiac asthma, drowning, sun stroke, hay fever, cold in the head, and excess fat.

"Seizures continued of 'magnetic ray' instruments and ozone generators that have been the subject of court actions for the past decade. While no new sources of supply have been located, distribution of such devices for restoring and preserving health is apparently too lucrative to be discouraged easily, despite seizures, prosecutions, and injunctions to restrain interstate shipments. Ordinarily, air purifiers, humidifiers, and vacuum cleaners do not come within the jurisdiction of the Food, Drug, and Cosmetic Act. When their labeling or sales promotion includes claims for the prevention of disease, however, they become therapeutic devices. Seizures were made of a 'room conditioner', a 'room humidifier', and a vacuum cleaner for unwarranted health claims of a general nature, and a 'germicidal' lamp to be installed in furnace air ducts to kill polio germs.

"Thirteen seizures covered defective or dangerous devices: clinical thermometers that failed to register accurately, rubber prophylactics with holes, feminine hygiene devices that would endanger the user,

and ultrasonic devices without meters to indicate the energy output or adequate means of preventing overexposure.

"The first seizures of ultrasonic devices were also based on false and misleading claims for a wide range of diseases. The physiological effect of the forces produced by ultrasonic devices is not fully understood. The Food and Drug Administration took the position that distribution should be limited to specialists in the field of physical medicine who alone are competent to conduct the scientific investigations required to establish the efficacy of such treatment and the precautions necessary to protect the patient. Following preliminary studies by these investigators, sufficient information was obtained to permit the distribution of properly constructed and calibrated ultrasonic devices to practitioners licensed to use such equipment. There has been no agreement to the broad claims originally made for these devices; shippers have been advised to offer them simply as an adjunct in the treatment of osteoarthritis and bursitis.

Cosmetics and Colors

"One cosmetic preparation was voluntarily recalled from the market by the manufacturer. It was a liquid eye cream which irritated the eyes of some users. The five cosmetics seized included two with false claims of beautification, two alleged to be misbranded as to ingredients, and one containing non-certified coal-tar colors. Seizure of a product labeled 'shampoo, plus egg' is being contested by the manufacturer. The Government charged this name to be misleading on a shampoo containing only 1/180th of an egg in each application.

"The only cosmetic prosecution charged shipment of an eyelash preparation containing coal-tar colors. Such products caused irreparable eye injury before cosmetics were brought under regulatory control and most of them were driven from the market during the early days of enforcement of the 1938 Act.

"One coal-tar color was recalled by a manufacturer because it had been distributed without certification. Another manufacturer was fined $500 for shipment of uncertified colors to food manufacturers, under the false labeling 'certified'. The firm had been repeatedly warned that this practice was illegal.

Certification Services

"*Coal-Tar Colors.*—All coal-tar colors used in foods, drugs, and cosmetics (except hair dyes) must be from batches certified by FDA.

In 1953, 4,220 batches, representing 4,661,394 pounds, were certified, and 34 batches, representing 30,805 pounds, were rejected.

"*Insulin.*—Predistribution testing and certification of certain drugs which cannot be controlled adequately under usual regulatory procedures are provided by four amendments to the act. One of these amendments covers insulin preparations. Examination of 272 samples resulted in the certification of 43 materials for use in making batches of insulin-containing drugs and of 72 batches of insulin, 71 of protamine zinc insulin, 36 of globin zinc insulin, and 50 of NPH insulin.

"*Antibiotics.*—Three of the amendments cover the antibiotics, penicillin, streptomycin, dihydrostreptomycin, chlortetracycline (Aureomycin), bacitracin, and chloramphenicol. Examinations made of 17,401 batches resulted in the certification of 17,279. The remaining 122 batches were rejected for certification for failing to meet the following standards: Sterility (55), potency (47), moisture (8), pyrogens (7), syringeability (3), volume (2). Examinations of 964 official samples of certifiable antibiotics and antibiotic-containing feeds led to manufacturers' recalls of 41 batches from the market for loss of potency, excessive moisture, formation of a precipitate, or short volume.

Legislation and Regulation-making Activities

"No amendments to the Food, Drug, and Cosmetic Act were enacted during the fiscal year, but two bills on which hearings were held in the spring of 1953 were passed before the adjournment of the First Session of the 83d Congress.

"One was enacted to correct the defect in the language of the Act disclosed by a Supreme Court decision on authority for inspection. Remedial legislation was urged by the President in his State of the Union address to Congress and a bill was recommended by the Secretary. When finally enacted on August 7, the measure contained provisions going beyond the Department-sponsored bill, including requirement for a written comment by the inspector on conditions observed during sanitary inspections, and a laboratory report on analyses of samples collected at the plant to determine whether they are decomposed or contaminated with filth.

"An attempt by the Senate to define the scope of inspections of druggists' prescription files was rejected by the House. This legislative history makes it clear that prescription files are exempt from inspection except through search warrant proceedings.

"The second bill to be enacted substituted the generic chemical name 'chlortetracycline' for the trade name 'Aureomycin' in the certification provisions of the act. At the time this antibiotic was brought under certification, its chemical structure had not been established.

"Hearings were held on three other bills, without enactment in the First Session. Included were a proposal to simplify procedures for the establishment of food standards, a requirement that public eating places give adequate notice of the serving of foreign trout, and a bill to afford better protection to public health and to simplify procedures for establishing tolerances for poisonous pesticidal residues in foods. The Department endorsed the food standards proposal in full and the pesticidal bill in principle, but suggested that the latter be modified to improve its effectiveness. Department representatives testified against enactment of the trout bill on the grounds that the expense of enforcement would not be justified by its potential public benefit.

"Other bills proposing changes in the Food, Drug, and Cosmetic Act or its administration, which did not reach the hearing stage, included two bills to control new substances in foods and cosmetics, one designed to outlaw imitations of foods for which definitions and standards of identity have been established, bills to provide for the establishment of a district office at Detroit, several concerning the repacking of fresh vegetables and potatoes, one to extend controls over exports, and one to ban the addition of artificial color to citrus fruit.

"An amendment to the drug regulations issued in July 1952 provides for more informative labeling of prescription-only drugs than was formerly permitted, restricts distribution of such drugs to those trade channels which regularly serve licensed physicians and pharmacists, and requires more informative labeling on bulk packages which will make it possible for pharmacists to repackage the chemical with appropriate labeling. The regulations also exempt certain habit-forming drugs from the prescription class when they are used in combinations that are not hazardous.

"The only other regulations issued, apart from food standards which follow, were changes in fees for certain services rendered by FDA, a consolidation of the shrimp inspection regulations, and technical changes in the antibiotics regulations.

Food Standards

"The bread order establishing standards of identity for five kinds of bread and rolls became effective in August 1952, except for the exclusion (by omission from the list of optional ingredients) of 'softeners' containing polyoxyethylene monostearate. On petition of three suppliers of these compounds, two circuit courts of appeal had granted stays on this part of the order, pending rulings on their appeals against this exclusion from the ingredients permitted by the standard. One court affirmed the order, the Supreme Court refused to review the decision, and the case was finally dismissed in the other circuit. The stays were removed and by the end of the year the bread standards were in effect in all respects.

"A final order became effective amending the definition and standard of identity for oleomargarine, permitting the use of citric acid and certain citrates to combat development of undesirable flavor in oleomargarine and the optional use of synethetic vitamin A and vitamin A from certain other sources not previously permitted. It also increased the minimum level from 9,000 units to 15,000 units of vitamin A per pound when used for vitamin fortification, and established 'margarine' as an alternate name for oleomargarine. During the year a petition for review was made on application of a firm selling vitamin A from fish oil, but the court dismissed the petition on its merits.

"A final order, amending the standard of identity for canned mushrooms, permitting as optional ingredients only salt and a limited amount of ascorbic acid, and establishing a standard of fill of container for canned mushrooms, became effective in December 1952.

"The ice cream hearing, part of which was held in 1941, and which was reopened in January 1951, was in session intermittently until December 31, 1952. The hearing was greatly prolonged by testimony concerning the safety and suitability of the polyoxyethylene type of emulsifiers for use in ice cream and related products.

New Court Interpretations

"The Supreme Court affirmed a decision of the Court of Appeals for the Ninth Circuit that the act does not require manufacturers to permit inspections. Corrective legislation is discussed . . . [at page 742].

"Petitions for certiorari were denied by the Supreme Court in five cases. Two were similar decisions by the Courts of Appeals for the Ninth and Tenth Circuits that the sale and delivery of a misbranded article to a person whose purpose to take it to his out-of-State home is known, constitutes delivery for introduction into interstate commerce, as prohibited by the statute.

"The Supreme Court also declined to review the decision of the Court of Appeals for the Fifth Circuit reversing a U. S. district judge who refused to enjoin a 'cancer clinic' and its operators from shipping drugs misbranded with false cancer claims.

"Court decisions on the exclusion of certain softeners from use in standardized breads are discussed under 'Food Standards'.

"The fifth denial of certiorari was on a petition by dealers convicted of misbranding horsemeat as 'chucks' and 'shanks' after its receipt in interstate commerce. The Court of Appeals for the Seventh Circuit upheld the conviction, overruling the defendants' claim that since they had already sold the meat the offense was not committed while the product was being held for sale. The court held that the test was not of ownership, but whether the article had reached the ultimate consumer. It also ruled that barrels are packages within the meaning of the act.

"The Court of Appeals for the Eighth Circuit upheld the conviction of a pickle processor for insanitary plant operations. It held that the act clearly defines what shall constitute a crime and that the terms 'insanitary conditions' and 'contaminated' are descriptive terms, commonly used and understood. The court also held that, despite the fact that the shipments were made shortly before the Government's factory inspections, the evidence justified the inference that the insanitary conditions noted in the factory were of a continuing nature.

"In upholding an order amending the oleomargarine standard, the Court of Appeals for the Second Circuit held that a consumer could be adversely affected by an administrative regulation and therefore had a right to ask for its judicial review.

"The Court of Appeals for the Fifth Circuit reversed a district judge's decision upholding seizure of a drug alleged to be misbranded. The appeals court held that the trial court abused its discretion in denying the claimant's motion for removal of the case to a district

of reasonable proximity to its principal place of business without showing good cause for denying the motion, as required by the act.

"Another appellate decision was based on methods of analysis used to establish the failure of a drug to meet the potency declared on its label. The product was not recognized in the U. S. Pharmacopeia at the time of shipment but was included in the next revision of that compendium. The Court of Appeals for the Ninth Circuit affirmed the conviction, holding that since the drug was not recognized in the U. S. P. at the time of shipment, the Government was not restricted to the U. S. P. method.

"The first court interpretation of the scope of the provision of the act dealing with imitation foods was handed down by the District Court for the Northern District of New York. It found a frozen dessert to be misbranded because it was similar to ice cream in all respects except that it contained soy fat and protein instead of milk fat and protein, but its label did not declare it to be 'Imitation Ice Cream'.

"The District Court of New Jersey ruled that cigarettes are drugs if therapeutic representations are made in the labeling. The court, in condemning the cigarettes as misbranded by an accompanying leaflet, held that the 'clear import of the leaflet is at least that the smoking of the cigarettes will make it less likely that the smoker will contract colds or other virus infections. This is enough to bring the product within the statutory meaning of "drug".'

Enforcement of Other Acts

"Tea imports examined under the Tea Importation Act again passed 100 million pounds, after a drop in volume in 1952. Of the 102,171,858 pounds examined, only 18,606 pounds were rejected for failure to measure up to standards set by the U. S. Board of Tea Experts. This amounts to less than 0.02 percent in comparison with 0.05 percent the previous year. Five appeals were entered in protest of these rejections but the U. S. Board of Tea Appeals sustained the FDA examiners' decision in each case.

"Six caustic poisons were seized, including drain openers, bowl cleaners, and a solder solvent. These products failed to bear the word 'poison' on the labels or bore it in letters smaller than prescribed by the Caustic Poison Act. One of the drain openers had been properly labeled originally but an advertising offer had been attached to the

container so that it covered the poison warning and the directions for treatment in case of accidental injury.

"No violations were discovered under the Filled Milk Act. No permits were issued for importations of milk from Canada under the Import Milk Act. One application was denied because Canadian veterinary officials reported unsatisfactory sanitary conditions on the dairy premises of the applicant.

Scientific Investigations and Some of Their Applications

"The Food and Drug Administration's intensive scientific investigations are limited to the development of new or improved regulatory tools and sounder and more specific knowledge of the products under its jurisdiction.

"The work of the scientific divisions is integrated to employ whatever specialized techniques and skills are required for each problem to be attacked. Often, two, three, or more divisions are working on different aspects of the same subject. Analysts in food, drug, or cosmetic laboratories devise methods to isolate measurable quantities of new ingredients in products, or to produce more precise methods for older components. When such action is indicated, the isolated substances are tested on experimental animals in nutrition and pharmacology laboratories, whose experts, along with the medical officers, evaluate the results in terms of public benefit or potential harm attendant to their use. If it is determined that the use of such substances is a violation of the act, the analytical methods are used for enforcement purposes.

"An example in 1953 was work on emulsifiers of the polyoxyethylene types. The chemists developed a method for the determination of the polyoxyethylene compounds in bread, to assist in the enforcement of the new bread standards which exclude such compounds because of lack of evidence of their safety. Pharmacologists, in continuing studies of the effects on experimental animals, found that rats fed a polyoxyethylene emulsifier show a reduction in intestinal flora and reduced growth. Nutritionists correlated retardation of growth and detectable tissue changes with alteration in the proportions of nutrients in the diet. There were marked effects on male animals on a diet with a substantial increase in fats. Chronic 2-year feeding tests using large numbers of rats in the control and experimental groups are still under way.

"Tests are progressing in the pharmacology laboratories to re-evaluate the safety of certifiable coal-tar colors, as to both direct toxicity and that resulting from metabolic changes through which colors may go. A new analytical tool, paper chromatography, has found application in the separation of coal-tar dyes under investigation.

"Studies of insecticidal residues and methods for their detection have received major attention in both chemical and biological laboratories. Not only are consumers affected by the use of such pesticides on growing crops, but there has been a relatively recent development in the use of vaporizers to disseminate pesticides in enclosed places where food may be stored, such as warehouses, restaurants, and in the home. It was found that lindane, when dispensed as a vapor, penetrates multiple layers of wax paper, kraft paper, and plastic film, and is toxic to test animals.

"Many insecticides owe their value (and also their toxicity to man) to the inhibiting effect they exert on a life-essential enzyme of the body, cholenesterase. Different insecticides have a wide range of inhibiting power. A test to gage the toxicity of various residues is being developed with good progress.

"The decision of manufacturers to stop selling coumarin for food use was discussed in the section '[Food, Drug, and Cosmetic Act] on . . . Food Front [—Health Hazards]'. FDA chemists devised new techniques by paper chromatography for a rapid test for the presence of coumarin, or any of four other commonly used vanilla-like flavoring substances. To meet other new situations it was necessary to improve methods of analysis for mercury to detect seed wheat treated with colorless mercury compounds; likewise to improve methods for pesticidal residues in vegetable oils, and to determine the diphenyl absorbed by citrus fruit from wrappers impregnated to retard spoilage.

"Chemical and microanalytical work to detect spoilage and filth contamination, like many other FDA scientific studies, can never be considered finished. It is a continuous process of adding bit by bit to the knowledge already acquired until the sum total can be used effectively as a regulatory tool, to be improved when advances in precision equipment and added studies permit. Work of this type continued in many fields in 1953, including tests for filth in cream for butter making, fish packs showing progressive decomposition, spoiled frozen eggs, insect infestation of corn, rot and fly damage to tomatoes, and vita-

min C deterioration. Bacteriological studies continued on the isolation and identification of food poisoning bacteria, spoilage in shell eggs, and frozen pre-cooked foods.

"Enforcement of the economic provisions of the food law also requires continuous improvement of analytical methods. Such studies must be deferred, however, when methods are needed to meet some health problem. Methods developed or improved in 1953 included a simpler and more rapid test to determine compliance with the egg content requirements of standards for noodles, salad dressing, etc.; to detect the components of admixtures of cream and cheaper fats in frozen desserts; and to detect adulteration of lemon oil with cleverly manipulated cheapening agents.

"Studies toward the formulation of new food standards have been made on fill of container for canned tuna, the composition of citrus and citrus-base beverages, canned pineapple, and a number of frozen foods. Fill-of-container standards for canned fruits are under review. Standardization investigations require work in areas of commercial production so that all factors that have bearing on workable standards can be given due weight. Such investigations are time-consuming and expensive. Reduced appropriations will curtail a major part of this program.

"Among the drugs investigated were barbiturates with built-in antidotes which would serve as emetics in cases of over-dosage. As had been established earlier for ipecac, it was found in 1953 that zinc sulfate is too toxic to justify its use in barbiturates. This chemical produces hypochronic anemia and has toxic effects on bone marrow, kidney, and liver.

"Clinical studies of the effects of new drugs when they become widely used—in comparison with results in carefully controlled experimental investigations before they are released for distribution—have been limited by the resources available. This work is an essential part, however, of establishing the safety of new drugs, to which FDA is diverting increasing man hours in a period when work must be curtailed in many other areas. To aid in the interpretation of clinical studies, doses of chloramphenicol larger than those used in human therapy were fed to experimental animals for an extended time. This produced granulocytopenia and anemia, with the depression of the

erythroid element of bone marrow and the development of fatty livers. Similar studies are under way for other wide-spectrum antibiotics.

"A study of the incidence of antibiotic-resistant staphylococci in hospital patients and the general population is being carried out in cooperation with members of other organizations.

"FDA antibiotics specialists and veterinarians joined with the U. S. Department of Agriculture and interested manufacturers in an extensive project to determine the presence of antibiotics in the edible portions of poultry and hogs fed antibiotics at various concentrations in some of the new feeding schedules, in eggs from such poultry, and in the milk of cows treated with antibiotics for mastitis. The studies are planned to show how much antibiotics get into the food and how long they remain after feeding or treatment is discontinued. Methods for the determination of antibiotics in animal feeds have been improved. The new methods can be easily adapted for the detection of small quantities of antibiotics in blood, tissue, and body fluid.

"Routine examination of liver injections led to the observation that the vitamin B_{12} content of 1 cc. vials deteriorated rapidly while samples of the same lot of liver injection in 5 and 10 cc. vials did not. This called attention to an important problem and the industry has now made marked progress in its solution.

"Chemical, bioassay, and microscopic methods are used for drug testing. The field laboratories, which do a large portion of the chemical testing of drugs, do not have animal laboratories and other equipment required for bioassays, which are all made in Washington. For this reason, and because animal tests are usually slower, more costly, and do not always differentiate between various components of preparations, work to replace them with chemical methods is continually in progress.

"In 1953, chemical methods were completed for water-soluble conjugated estrogens and for epinephrine to replace the bioassay tests formerly employed. In each case the new method gives more complete information about the product being tested.

"Work on chemical methods to correlate the composition and therapeutic response of adrenal cortex extracts is in progress. These extracts are complicated mixtures of steroids which may cause several different responses. Methods have been developed for the determination of four of the active steroids present, and methods for other active compounds are under study.

"A new and more reliable chemical procedure was developed for the analysis of digitoxin tablets. The U. S. P. method was unsatisfactory because it did not distinguish between digitoxin and some of the other glucosides that might be present. The new procedure is being modified and applied to other preparations of purified digitalis glucosides.

"A chemical method was developed for measuring the amounts of each ingredient in mixtures of neomycin and dihydrostreptomycin.

"The bioassay of tubocurarine has been modified to promote the rapid recovery of assay animals and allow their frequent reuse for testing this drug.

"In the microanalytical field, studies were conducted on optical-crystallographic methods to identify 16 of the newer drugs.

"Studies of lubricating jellies containing the proportion of formaldehyde suggested by some manufacturers showed that it was not safe in those concentrations and the quantity of formaldehyde used must be lowered to protect daily users of the jellies from mucous membrane irritation.

"Investigation of the mucous membrane toxicity (particularly irritation of the eye) of the new compounds known to be currently used in cosmetics for their emulsifying, antiseptic, and detergent effects continued, and the concentrations that are well tolerated were determined for many substances. The tests were extended to skin toxicity of these new components and safe concentrations for certain classes of agents were determined. Variations of individual members of other classes were so great that safe concentrations ranged from 1 to 100 percent.

"Continued investigation of thioglycolate hair waving preparations showed a derangement of carbohydrate metabolism when these preparations penetrate the skin. Diabetic rats exhibited marked respiratory and urinary changes when thioglycolates entered the circulatory system through skin abrasions.

Enforcement Statistics

"The percentage of time to be devoted to each class of products is determined tentatively at the beginning of the fiscal year under a planned project system of operations. The seriousness and extent of

TABLE 2.—Enforcement Activities During Fiscal Year 1953

Item	*Percentage distribution of enforcement time*	*Number of factory inspections*	*Number of samples collected*
Domestic	90.3	12,502	23,361
Foods	65.3	9,982	15,297
Drugs and devices	31.4	2,176	7,616
Cosmetics and colors	2.7	274	315
Other acts and miscellaneous	0.6	70	133
Import	9.7	0	13,159

violations anticipated in each industry, and its volume of output, are the controlling factors in the apportionment of enforcement effort. Unexpected events may require modification of the percentage of time allocated to different projects.

"The seizure actions shown in table 3 are usually terminated before the end of the year, except for a few in which court contests are pending. In some cases, criminal prosecutions and injunctions instituted in one fiscal year are not actually terminated in Federal court until the following year or even later. The number of samples on which actions are based always exceeds the number of actions. A variety of articles may be seized in a single shipment, while criminal actions are usually based on a number of counts and each count usually represents a single shipment.

"In the 276 criminal actions terminated during 1953, the fines paid or assessed in cases pending on appeal, totaled $146,578. The heaviest

TABLE 3.—Number of Samples on Which Criminal Prosecutions and Seizures Were Based and Number of Court Actions Instituted During Fiscal Year 1953

Item	*Total*		*Criminal prosecutions instituted*		*Seizures accomplished*		*Injunctions requested*
	Violative samples	*Actions*	*Violative samples*	*Actions*	*Violative samples*	*Actions*	
Total	3,305	1,782	1,137	329	2,168	1,442	11
Foods	2,234	1,403	583	177	1,651	1,220	6
Drugs and devices	1,043	366	540	150	503	211	5
Cosmetics and colors	11	6	5	1	6	5	0
Caustic poisons	17	7	9	1	8	6	0

TABLE 4.—Import Inspections and Detentions During Fiscal Year 1953

Item	*Total*	*Inspected and refused entry*	*Inspected and released*
Total	31,971	5,087	26,884
Foods	29,450	4,030	25,420
Drugs and devices	2,364	1,022	1,342
Cosmetics, colors, and miscellaneous	157	35	122

fine in a single case was $10,000. In 45 actions the fines were $1,000 or more. Jail sentences were imposed in 17 cases involving 19 individual defendants. The sentences ranged from 2 months to 1 year, and averaged 8 months and 8 days. For 15 defendants the jail sentences were suspended and they were placed on probation.

"Records of actions terminated in the Federal courts were published in 1,373 notices of judgment issued during the year." **[The End]**

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tive committee of the Section in an adjoining room, immediately after the morning session.

Afternoon Session, beginning at 2 o'clock

Presiding Officer: Chairman of Section

Discussion of Amendment to Federal Food, Drug, and Cosmetic Act, for Regulation of Chemical Additives in Food

Dr. Arthur L. Miller of Washington, D. C., Member of Congress and former member, House Select Committee to Investigate the Use of Chemicals in Foods and Cosmetics

W. C. Foster of Washington, D. C., President, Manufacturing Chemists' Association, Inc.

Papers

Edward Brown Williams of Washington, D. C., Attorney at Law
Subject: "Price Restitution Enforcement of Federal Food, Drug, and Cosmetic Act"

Michael F. Markel of Washington, D. C., Attorney at Law
Subject: "Food Standard Progress of Federal Food, Drug, and Cosmetic Act"

Sol. A. Herzog of New York City, Attorney at Law
Subject: "Durham-Humphrey Amendment of Federal Food, Drug, and Cosmetic Act"

Report on Products Liability Law

William J. Condon of New York City, Attorney for Swift & Company

Floor Discussion

New Business

Adjournment

Mr. Dunn cordially invites all interested persons to attend this meeting.

The section, established in 1945, is the pioneer bar organization in the field of this law.

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• FDA REPORT FOR OCTOBER •

Ninety-two shipments of foods, drugs, devices and cosmetics were removed from the consumer market in October for alleged violations of the federal law, according to a report released by the Food and Drug Administration on November 24, 1954.

The largest lot seized consisted of 299,600 pounds of popcorn found in a warehouse heavily infested with insects and larvae. Twelve seizures involved drugs and devices misbranded with false and misleading claims or which were below the required standard of purity or potency.

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